25 November 2023

SAMED (the South African Medical Technology Industry Association) submission of comments on

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)
REGULATIONS RELATING TO MEDICAL DEVICES as contained in Government Notice NO.3817, Government Gazette #49189, published on 25 August 2023

for the attention of the

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Director: Public Entities Governance, mihloti.mushwana@health.gov.za

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Introduction

SAMED – The South African Medical Technology Industry Association – represents the interests of 152 medical device, medical equipment and in-vitro diagnostic (IVD) (collectively referred to as "medical technologies") companies in South Africa. SAMED is committed to ensuring a sustainable, ethical and transformed medical technology industry.

SAMED and its members have been engaging on medical device regulations since the early 2000's and has built up significant collective memory and experience in medical device regulations. Many of its members, have vast experience in regulatory regimes in many jurisdictions. SAMED therefore believes that it could enrich and enhance the current process.

SAMED supports the promulgation and implementation of regulations that –

- Are **appropriate for the South African market**, i.e. acknowledge the structure of the market, the medical device supply chain and the fundamental difference from medicines regulation. In administrative justice terms, appropriateness means reasonable, rational and proportionate. It must also be **appropriate for medical devices (including IVDs)**, for example regarding medicines wholesaling as duplicative for medical devices.
- Leverage on **international experience** and that of **recognised jurisdictions**, not creating duplication (i.e. unnecessary wastage of resources) and/or systems that are unique to South Africa.

- Ensure **speedy market access** for devices, the life cycle of which can be 2 to 4 years in many instances. Creating various steps in regulatory processes, each with the potential of delay or repeat-engagements (as seems to be the case when evaluating the proposed fee structure also recently released for comment), is an example of aspects that hamper market access and, therefore, patient access to care, and competition in the market. The absence of timelines, as is required by section 35, remain a concern.

SAMED commends SAHPRA for introducing the regulatory framework consultation and for taking the necessary steps to elevate its regulatory framework. Doing so will most certainly improve access to safe and effective Medical Devices and In vitro diagnostics. We understand risk-based, fit for purpose regulation will not happen overnight – and it can best develop when there is a healthy partnership between the regulator and industry. Therefore, we offer our continued support and following comments based on international best practice (IMDRF, WHO and other).

To facilitate SAHPRA's ability to implement a roadmap and pathways to registration of medical devices (MDs) including IVDs, while ensuring uninterrupted access to safe and effective product and building a transparent and efficient regulatory framework that attracts innovation, we recommend SAHPRA leverage its authority as granted in the Act and align to international best practice. Specifically, we recommend SAHPRA:

(1) Exclude class A and B low risk products from registration and technical review
(2) Practice reliance on the original GHTF countries and recognized institutions (e.g., the WHO and Notified Bodies) and provide an abridged pathway for class C and D MD and IVDs.
(3) In the case of emergency use, practice recognition on the original GHTF countries and recognized institutions (e.g., the WHO and Notified Bodies) so long as the manufacturer can prove the products are sufficiently similar[1].

Rationale:

As a matter of law, the Medicines and Related Substances Act 101 grants the authority to the Minister and the Authority to practice reliance. **See 2.B. Functions of Authority**. The text of the Act states, the Authority may "[L]liaise w/any other regulatory authority or institution and may *without limiting the generality of the power*…exchange information with and receive information from any such authority or institution…*and cooperate w/any regulatory authority in order to achieve the objectives of this Act*." Please note the term "and" in the text of the statement above.

[1] Sameness of product. For the purpose of this document, sameness of product means that two products have identical essential characteristics (i.e. the product being submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same). All relevant aspects of drugs, medical devices and in vitro diagnostics, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g. same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredients, same quality of all excipients). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same. The impact of potential, justified differences should be assessed by the manufacturer (for the purpose of this document, manufacturer also means marketing authorization holder) and the relying national regulatory authority (NRA) in determining the possibility of using foreign regulatory assessments or decisions. WHO, Good reliance practices in the regulation of medical products: high level principles and considerations, Annex 10, page 243.

This reading is interpreted to mean an agreement is not required per the Act in order to cooperate with any other authority or institution in order to meet the objectives of the Act.

The Act does not require a registration for every MD/IVD. Nowhere does it state every MD/IVD will be registered. *It requires an application for every registration*. (Act Section 15, Registration of medicines, medical devices, and IVDs). It also does not define what must be in the application for registration and leaves this up to the Minster/Authority. Therefore, it is within the purview of the Minister/Authority to determine when a registration is required and what is to be included in a submission for registration. As a result, the Act allows SAHPRA to take a risk-based approach. Specifically, low risk product does not require registration and it also does not require the same level of review as class C and D. In addition, Section 35(6) of the Act on Regulations, "Regulations may be made under this section in respect of particular ...medical devices or IVDs or classes or categories of... medical devices or IVDs… and ***different regulations may be so made in respect of different... medical devices or IVDs or different classes or categories thereof***. Lastly, in support of our recommended risk-based approach, **Section 36 of the Act grants the Minister broad authority to exclude any medicine, Scheduled substance, medical device or IVD from operation of Act.**

> The Minister may, on the recommendation of the Authority, by notice in the Gazette exclude, subject to such conditions as he or she may determine, any...medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice. – *Section 36, Exclusions*

To support each of the arguments above, we make reference to Section 2B Role of Authority which states they have a responsibility to "Ensure efficient, effective, registration of MD/IVDs and to ensure the process for registering MD/IVDs is transparent, fair, objective, and concluded timeously". To meet these objectives given the available resources and avoid interruptions in patient access to safe and effective medical devices, we recommend the Minister exercise his/her exclusion authority and exclude class A and B from the registration and technical review process, and implement reliance and recognition pathways for class C and D and emergency use authorization respectively. This is not only within the purview of the Minister's authority; it is in line with international best practice (US FDA, Singapore, and Brazil) as well as the WHO's Global Model Regulatory Framework (GMRF).

We recommend SAHPRA practice recognition on Medical Device Single Audit Programme (MDSAP) and ISO 13485 certificates in lieu of performing a country specific inspection. This recommendation is supported by the text of the Act. The Act grants the authority to authorize inspections but it does not prescribe when such inspections need to be activated or that all inspections must be performed by the Authority. In addition, the Act grants broad authority to cooperate with any authority in order to achieve the objective of the Act[2]. In addition, Section 36 of the Act grants the Minister broad authority to exclude any medicine, scheduled substance, medical device or IVD from operation of Act. As a result, it is within the Authorities preview to rely on MDSAP and ISO 13845 certificates in lieu of performing a country specific inspection.

[2] The Act authorizes the Authority to "[L]liaise w/any other regulatory authority or institution and may *without limiting the generality of the power*…exchange information with and receive information from any such authority or institution...*and cooperate w/any regulatory authority in order to achieve the objectives of this Act*." See 2.B, Functions of Authority.

Rationale: We advance that recognition on trusted inspections performed will help relieve limited resources to focus on critical in country activities such as in country inspections and post market surveillance and elevate the overall health and safety of the South African population. And as a member of IMDRF, it will demonstrate South Africa's commitment to international best practice.

We recommend SAHPRA define Adverse Events ("AE") based on the IMDRF and WHO Global Model Regulatory Framework definitions. The term AE is not defined in the Act and therefore must be defined in lower level regulation. SAHPRA has advanced a draft definition of an AE that is not aligned with international best practice. The draft definition will create an exorbitant about of unnecessary work for SAHPRA and make it difficult to collaborate with other IMDRF countries to proactively prevent AEs. Regarding adverse events, the term is nowhere defined in the Act and therefore we recommend it be defined according to international best practice in lower level regulation. We also recommend the adoption of the IMDRF listed exclusions[3]. Specifically, we recommend SAHPRA implement the following reportability criteria:

An event becomes reportable to the Regulatory Authorities when the **manufacture becomes aware** of an event involving their device:

- May have caused or **contributed to a death, serious injury** or serious deterioration in health of a patient, user or other person.
- Has malfunctioned and would be **likely** to cause or contribute to a death, serious injury or serious deterioration in health if the malfunction were to recur.

Rationale: In order to allow SAHPRA to focus their limited resources on those AEs with the greatest risk to patients, we also recommend a staged approach to the implementation of AE. Specifically, we recommend SAHPRA implement AE reporting for death and serious injury cases first. This will help ensure SAHPRA has adequate resources to process those cases with the highest risk to patients. Once SAHPRA has demonstrated it has adequate resources to process the workload surely to be created by reporting potential adverse event cases (the vast majority of reportable events) we recommend SAHPRA follow other recognised and established regulatory frameworks to implement Summary Reporting. Taking this approach ensures the best of the best for SAHPRA and establishes a sustainable model for AE reporting to ensure patient safety.

We recommend SAHPRA review only those changes (amendments/variations) likely to affect the safety, performance and/or quality of the medical device or IVD. SAHPRA can operationalize this by adding the definitions of significant and non-significant changes to their regulation and implementing regulator reviews for significant changes only.

Rationale: IMDRF does not have a guidance that defines significant (major) and non-significant (minor) changes. In addition, some developing guidance (e.g., GHWP) does not align with the WHO. For this reason, we recommend leveraging the WHO's definition of significant and non-significant change and implementing a risk-based approach to the review of these changes. According to the WHO, minor (non-significant) changes have little potential to impact the safety, performance and/or quality of the medical device while substantial changes (significant/major changes) are likely to

[3] Medical Devices: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices – GHTF/SG2/N54R8:2006

affect the safety, performance and/or quality of the medical device[4]. As a result, only those changes that significantly impact safety and effectiveness should be reviewed by an authority prior to marketing the modified product. All other changes should be documented internally according to the manufacturers established Quality Management System ("QMS") and subject to inspection. Keep in mind, just because a product change is not reported to and reviewed by the Authority, it does not mean the change has not been thoroughly scrutinized. Manufactures are required to perform a risk assessment of each product change and document their decisions and rational in the device record as to the risk of the change and whether reporting to an authority is needed. These records are subject to inspection. Leveraging the WHO's definitions of significant and insignificant changes will help SAHPRA make wise use of their limited resources to review those changes with the highest risk to patients. In addition, SAHPRA can rely on a number of inspections (NRA, WHO, NB, MDSAP, ISO 13485) to ensure the manufacturers QMS is strictly adhered to and their decisions are sound.

To further align with international best practice and comply with WTO obligations, we invite SAHPRA to adopt internationally recognized standards and avoid requiring country specific standards. While it may be unavoidable to implement country specific requirements in local standards, the country is obliged to justify through scientific evidence why the local requirement is necessary. We invite SAHPRA to review all country specific standards requirements that differ from an international best practice and ensure their WTO obligations have been fulfilled.

Rationale: The Act does not specify that South African standards must be met. Rather it states, "The Authority must, in order to achieve its objects - ensure the efficient, effective and ethical evaluation or assessment and registration of…medical devices and IVDs *that meet defined standards* of quality, safety, efficacy and performance, where applicable". Therefore, SAHPRA is authorized by the Act to avoid South African specific standards requirements to demonstrate conformity to the Essential Principles.

We would respectfully like to draw your attention to Section 22H (1)(a) of the Act which states, "No wholesaler shall purchase medicines, Scheduled substances, medical devices or IVDs from any source other than from the original manufacturer or from the primary importer of the finished product." We agree this this provision is crucially important to ensure the legally responsible manufacturer and the initial importer can meet and continue to meet their legally binding Quality Management System requirements including post market controls. Provision 22H (1)a) allows the manufacturer trace where their products are at in the country. There is speculation as to whether South Africa is abiding by and enforcing this provision. If it is the case that this provision is not followed, manufacturers are at risk of losing traceability to their products – which makes it very difficult, if not impossible, to meet its post market surveillance obligations including recalls. We respectfully invite SAHPRA to review the provision, contrast it with current practice and take the necessary steps to ensure it is abided by.

We would be remiss if we did not broach the topic on in country lot testing – either premarket or postmarket. **We recommend SAHPRA implement a risk-based approach to in country lot testing.** The topic of lot testing has been discussed amongst mature regulators and the WHO.

[4] WHO Global Model Regulatory Framework, Annex 3, page 251.

Mature regulators (United States of America, Singapore, Brazil, Health Canada, and Australia) do not perform blanket lot testing before or after market authorization. They maintain the right and authority to activate lot testing if there is a safety concern related to a specific product. Additionally, the WHO recently published their guidance for lot testing. The WHO Global Model Regulatory Framework ("GMRF") states, "Countries may implement a system of risk-based lot verification of high-risk IVDs (Class D), either before distribution to users, post distribution or before they are put into service." See the GMRF, page 207. In addition, the WHO GMRF states, "In general, the routine testing of medical devices including IVDs (either imported or locally produced) by the NRA is not a cost-effective use of limited resources and is not recommended." See the GMRF, page 257-58. Finally the WHO GMRF supports this approach by calling attention to the manufacturers' legal responsibility to ensure the quality and safety of their medical products - "The Quality Manufacturing System (QMS) already requires the manufacturer to ensure products released meet the stated claims, performance and specifications. For example, manufacturers are required to have quality checks throughout the entire manufacturing process including final lot release testing. IVDs require control testing before patient testing. Control testing is designed to ensure the IVD test performs as intended even after the product has left the manufacturer. Manufacturers are also required to document all complaints received, determine if an investigation is needed, track and trend complaints, report adverse events, and update the product or even recall it." We would lastly add that the Act does not authorize the Authority to perform blanket lot testing. It states, in Section 28 Power of Inspectors, that samples can be collected within the scope of inspection and inspectors are required to a certificate stating the Minister has deemed them an inspector. Therefore, the Act does not authorize broad collection of samples for testing. From the reading of the Act, we can only conclude a risk-based approach was intended. We therefore call on SAHPRA to implement a risk-based approach to in country lot testing and implement a lot testing option for high-risk product (class D) and in such cases where there is evidence of a quality or safety issue for a particular product. This will align SAHPRA to the international best practice and ensure focus on those issues with the highest risk to patients.

Furthermore, we wish to address the labeling requirements, particularly concerning the requirements to include the license number on each device once registered. While we understand the validity of this requirement for traceability and compliance purposes, it inadvertently poses a significant challenge. Specifically, obligating distributors to update labeling to include the license number effectively reclassifies them as manufacturers under regulatory definitions. This shift blurs the distinct roles within the supply chain. Such a requirement could disrupt the distribution process and potentially impact the availability of these products. Therefore, we urge SAHPRA to reconsider this aspect of labeling, perhaps by seeking alternative methods for maintaining traceability that do not inadvertently alter the role of distributors in the supply chain.

While we first encourage recognition or reliance on market authorization granted from mature regulators (original GHTF countries) and recognized institutions (WHO and Notified Bodies), we would also like to invite SAHPRA to implement appropriate evidence requirements, if deemed needed, for IVDs and MDs[5, 6]. However, it is essential to acknowledge the distinct evidence requirements for MDs and IVDs, as highlighted by the IMDRF– because these product types are fundamentally different.

[5] Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation.
[6] IMDRF MDCE WG/N56FINAL:2019: Clinical Evaluation: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n56.pdf

For IVDs, IMDRF (GHTF) states, "When placing an IVD medical device on the market the manufacturer must have demonstrated through the use of appropriate conformity assessment procedures that the device complies with GHTF's Essential Principles of Safety and Performance of Medical Devices (EPs). Generally, from a clinical perspective, it is expected that the manufacturer has demonstrated the device achieves its intended performance during normal conditions of use in the intended environment (e.g., laboratories, physician's offices, healthcare centers, home environments) and in the intended use population. As IVD medical devices are used for the examination of specimens derived from the human body, the characteristics of clinical evidence are different from medical devices…".

In the context of MDs, IMDRF states, "When placing a medical device on the market, the manufacturer must have demonstrated through the use of appropriate conformity assessment procedures that the medical device complies with the Essential Principles of Safety and Performance of Medical Devices (the Essential Principles). Generally, it is expected that the manufacturer has demonstrated the medical device achieves its intended performance during use according to its labelling (i.e., information supplied by the manufacturer) and that the known and foreseeable risks are minimized and acceptable when weighed against the benefits. Any claims made about the medical device's safety, clinical performance and/or effectiveness should be supported by suitable evidence." The clinical evidence may involve leveraging clinical experience and literature reports of comparable devices or compliance with recognized standards, especially for devices based on well-established technologies.

Due to the differences that inherently exist between MD and IVDs and given comprehensive IMDRF guidelines, we recommend SAHPRA incorporate specific evidence generation requirements for both IVDs and MDs as outlined by IMDRF when reliance is not feasible.

SAMED's approach to this submission

SAMED's comments, as contained in this submission, are based on the differences between this revised version of the regulations ("the current draft"), and those previously published in Government Gazette 40480 on 09 December 2016 ("the current regulations"), and Government Gazette 44593 on 21 May 2021 ("the previous draft").

The submission is structured to show:

- industry's agreement with changes in the current draft
- regulations that require deletion, changes and/or further discussion
- regulations that have been removed that should be reinstated
- regulations that should be in this draft, in terms of Section 35 of the Medicines Act.
- a collaborative set of comments from multiple stakeholder voices across the sector

Given what is outlined in the Introduction, SAMED strongly propose that the final version of the Draft Regulations be **workshopped.** SAMED requests that the Regulator incorporate and adjust the draft regulations to cover all valid comments made by SAMED and others during the public comment period. Thereafter there should be an opportunity to workshop all clauses which require further discussion to find alignment with industry, prior to the final publication of regulations for medical devices. This approach will ensure that both SAHPRA and SAMED and its members' contentions are understood, and that there is an opportunity to consider the practicalities and operationalization of medical device regulations. SAMED is concerned that, without the inclusion of these recommendations and cautions, an opportunity may be missed to finalise the best possible

regulatory framework. Not doing so could also give rise to consistent challenges, and/or substantial section 36 exemption applications and/or section 24A appeals, as companies try to navigate the regulatory framework. SAMED's proposal would serve to avoid unnecessary challenges and to enhance the regulatory process for both the Regulator, and companies.

Overall comments

The following comments pertain to the **whole set of draft regulations and also the empowering legal- and guidelines framework.** It is not limited to individual clauses:

(a) **IVD inclusion .** IVDs, that had been part of medical device regulations in the current regulations of 9 December 2016, remain excluded from the regulations headings and in some clauses. These should be reinstated, where appropriate, to read "medical devices including IVDs".

(b) **Wholesaler licence.** All references to wholesaler licences should be removed. The heart of this problem lies in the "as is" application of the medicines system to medical devices. Wholesalers are not a distinct part of the medical device supply chain and are not recognised as a separate category of medical device "establishment" in international guidelines. ISO13485 states that distributors may source from other distributors. Whereas for medicines "distributors" refer to logistics providers, distributors of medical devices are importers and on-sellers in the local market. Section 22H of the Medicines Act then leads to the unfortunate situation that some distributors are unable to sell to provincial depots with wholesaler licences, or importing distributors are required to supply through wholesalers to hospitals and other health facilities.[7] The oversight of wholesaling / logistics activities is managed via the QMS and/or contractual agreements, as part of ISO13485. Companies that distribute medical devices or IVDs should be able to source supplies by importing, or from local manufacturers/distributors.

The Inclusion of a wholesaler licence for medical devices have already caused significant challenges in the market. It will continue to incentivise companies to import rather than to source locally, and have led to companies being excluded from public sector supply. To reduce unnecessary complexity and avoid unintended consequences, there should be no separate license for wholesaler. It would be easy enough to include distribution activities into the manufacturing / importing licence.

Wholesaling can remain in the medicine regulatory framework. SAMED is alive to the fact that sections 22C and 22H create the impression of a supply chain that necessitates both medicine- and medical device wholesalers and wholesaling licences. SAMED urges SAHPRA to attend to this

[7] See, for example, https://www.sahpra.org.za/wp-content/uploads/2023/02/SAHPGL-MD-07_v3-Guideline-on-Questions-and-Answers-Licensing-of-Medical-Device-Establishments.pdf

error in the Medicines Act, and, consider an exemption to it, whilst ensuring that the medical device regulations are corrected by not limiting the definition of a distributor to the importer of a medical device.

(c) **Medical Device / IVD Registration:**

(i) SAMED has, through the years, raised the fact that a single medical device may be imported and/or distributed by more than one company. This is a significant difference from medicines, where a single product is always linked to a single section 22C-licence holder. There is to date no indication as to how this matter will be handled, i.e. the registration of the same medical device by multiple distributors. Not only would such a process be redundant and inefficient, it also creates the risk of differing outcomes.

(ii) The Essential Principles of Safety and Performance are internationally recognised documents that contain prescribed requirements and standard formats, pursuant to the Regulator's statutory mandate in section 2B(2) of the Medicines Act in terms of alignment and recognition. Section 2B(2) reads as follows:

(2) The Authority may—

(a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of—

(i) matters of common interest; or

(ii) a specific investigation; and

(b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

There is no indication in the proposed draft regulations as to how SAHPRA intends to implement this for medical devices and IVDs. Such provisions would be necessary in order to prevent the section from being implemented in a manner that gives SAHPRA an unfettered discretion, i.e. constitute an unlawful delegation of legislative power. Although SAMED welcomes recognition models, such as "Reliance", its inclusion in regulations and subsequent implementation documents (i.e. Guidelines) is vital.

The 2019-version of the Essential Principles document has been archived[8] by SAHPRA, and it is not clear what the regulatory approach will be. We recommend SAHPRA implement the same internationally accepted practices to avoid country specific regulation that may complicate the registration process, make it more difficult to reply on approvals from other mature regulators, and delay timely access to treatments. For example, the IMDRF "Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices" already outline internationally accepted essential principles.

(d) **Classification and requirements:**

(i) In the medical device regulatory history, it was always understood that low-risk medical devices would not require registration, and would only have to be listed. Previously, Class A devices were exempted from being listed on establishment license. It is unclear whether Class A devices will be subject to full registration process, as it could be included in Draft regulation 8(2). SAMED recommends SAHPRA maintain that Class A devices, as only requiring listing, and strongly recommends the inclusion of a specific regulation to provide for such listing, failing which the provisions of regulation 8 would have to apply in its totality. The approach proposed by SAMED would be consistent with the approach in other regulatory jurisdictions.

SAMED therefore proposes that the regulations make provision for a simple listing or notification for Class A and B medical devices/IVDs. It should be noted that several global regulators, such as USFDA, Health Canada, TGA, and ANVISA, have employed a risk-based approach in their regulatory framework and do not typically require approval of low-risk devices. This allows for allocating and prioritizing resources in assessment of the medical devices.

Regulating lower class devices will not only add to the regulatory burden on SAHPRA, it will also add very little value, decrease access and increase the cost of the device. It would also require forcing such low-risk devices into regulatory models designed for higher risk devices, which would be irrational, costly, disproportionate and unnecessary in view of the regulatory objective of ensuring safety, quality and performance.

(ii) In terms of changes to classification, SAMED recommends that South African regulations align with global rules on device classifications. Changing the international classification of items in South Africa will add additional requirements which could result in limiting supply of

[8] https://www.sahpra.org.za/document/medical-device-ivd-essential-principles/

medical devices to South Africa, and loss of access to technology for patients. It will also hamper the implementation of section 2B(2) and Reliance.

(iii) Industry recommends that STED submission (including validation, clinical trials, etc) for registration of all classes of medical devices or IVDs not be required, where these products have been reviewed and accepted by recognised international regulatory authorities.

(e) **Good Regulatory Practices.** SAHPRA should evaluate its approach and the draft regulations against the principles of Good Regulatory Practices for the best possible outcome of engagement with stakeholders and fulfilment of their mandate to protect the public. The Department of Monitoring and Evaluation requires a "SEIAS" - Socio Economic Impact Assessment System[9] to ensure that all regulatory proposals make economic and social sense. Given the large numbers (hundreds of thousands) of medical devices and IVDs which stand to be covered by the proposed regulations, such an assessment would be necessary. In addition, SAMED proposes that the wealth of resources relating to the principles that should underpin Good Regulatory Practice, be adopted by SAHPRA, and that it finds expression in future medical device regulatory endeavours. The table below list some of those sources:

Good Regulatory Practices (GRP): A formalized, mandatory, whole-of-government policy, that defines the common and transparent rules by which regulatory agencies develop technical regulations for all regulated sectors (i.e., cross-sector, transverse, horizontal, foundational) following international standards for GRP. GRP is the quality control mechanism for the development of regulations, ensuring on a continuous and systematic basis that government rules are relevant, of the highest quality, cost-effective, internationally aligned and least economically restrictive amongst alternatives of the same purpose. GRPs create a professional process to rule-making by adhering to a transparent and participatory rule-making process, and to evidence-based decision making. *Reference:* https://www.uschamber.com/sites/default/files/good_regulatory_design_paper_-_4-24-2017_-_final.pdf, *pgs 5 and 6* WHO Good regulatory practices for regulatory oversight of medical products *The OECD Report on Regulatory Reform*; Organization for Economic Cooperation and Development, Paris; 1997.

[9] https://www.dpme.gov.za/keyfocusareas/Socio%20Economic%20Impact%20Assessment%20System/Pages/default.aspx

https://www.oecd.org/gov/regulatory-policy/2391768.pdf
OECD recommends as a key principle that regulations should "produce benefits that justify costs, considering the distribution of effects across society".

(f) **Regulator capacity building**

SAMED believes that SAHPRA, with its various sub-departments, should consider the maturity of the regulatory framework and build staffing capacity in disciplines more aligned with medical devices and *in-vitro* diagnostics, before implementing advanced aspects of medical device regulation. Section 35(1) (xxxvii) stipulates that regulations should provide for the "scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of medicines, medical devices and IVDs". The proposed draft regulations do not include any such provisions.

(g) **Regulator service levels:**

(i) In the current, 2016 regulations, the regulation on expedited registration was removed and has not been reinstated: this is a concern because of the short life cycle of medical technologies. The absence of timelines, as is required by section 35, increases the risk of products being "in process", requiring updates and leading to a continuous toing and froing relating to such products.

SAMED proposes that medical devices be registered within 90 days to avoid obsolescence and barriers to access to technology for South African patients. International examples include: Australia can generate licenses within 2-4 weeks with reliance in USA or EU. UK has immediate reliance with the EU.

(ii) In spite of the explicit provision in section 2B(1)(a), namely:

(1) The Authority must, in order to achieve its objects—

(a) ensure the efficient, effective and ethical evaluation or assessment and registration of … medical devices and IVDs…;

there are no provisions in the proposed draft regulations that give effect to these principles. The regulations do not commit the Regulator to a Service Level Agreement.

SAMED would like to see assurances in regulations that medical device registrations will be efficient and cost effective and will not result in lengthy backlogs as has been seen with medicines registrations. As stated above, section 35(1) (xliii) stipulates that there should be regulations "relating to time frames for the consideration of applications by the Authority".

(iii) There is no clear commitment in these regulations to publish registration particulars in electronic format on a website. Regulation 9 of the proposed regulations should be amended to provide for such electronic publication.

(h) SAMED welcomes the deletion of the regulation "Manner and Conditions for Allowing International Tendering" per our comments submitted on 19 August 2021.

(i) **"Authorised Representative" / Management Responsibility:**

There has been considerable uncertainty in relation to the "Authorised Representative", and the false analogies with the pharmaceutical "Responsible Pharmacist", whose obligations are outlined in a different law, the Pharmacy Act.

The following requires clarification: the definitions and responsibilities of the authorised representative, the legal manufacturer and the "holder of the certificate of registration" (given that more than one entity may distribute the same device, unlike medicines where the section 22C licence and the section 14 registration are linked and pertain to a single product and a single licence-holder). SAMED recommends harmonisation with IMDRF definitions and that an internationally-aligned approach be followed. SAMED recommends that the function of the authorised representative should only pertain to communication or linkage between the legal manufacturer and the regulator as the legal manufacturer takes responsibility for quality and safety of a medical device.

The proposed SAHPRA workshop with industry and other stakeholders should include an opportunity to discuss and clarify the roles, expectations and requirements of the various positions referenced in the regulations (i.e. authorised representative, legal manufacturer and holder of the

certificate of registration) to address any misunderstandings on the matter. The outcome of this discussion could lead to a guidance document to define the appropriate responsibilities.

(j) **Adverse event reporting**:

Adverse event reporting regulations are not harmonised with international norms and practices – it is recommended that the regulations adopt the definitions for serious adverse events, what events are to be reported and the timelines for reporting per the EU model. Refer to Appendix C.

(k) **Additional categories of medical devices:**

Provisions for "Research Use Only", borderline, combination devices, software as devices and biological medical devices are not included in the regulations and require a clear regulatory process. Combination medical devices are included in the definition in the Medicines Act, but a regulatory pathway is required. The same with biological medical devices, some of which may fall under the human tissue regulations issued in terms of the National Health Act, 2003. Software as devices, and AI as medical devices also require regulatory clarity.

(l) **Labelling and Instructions for Use [Draft Regulations 5, 6 and 7]:**

(i) There is a requirement for the "registration number of the medical device" and "name and physical address of the holder of the certificate of registration" to be contained in the labelling. This requirement may require suppliers of medical devices to create special labelling for product coming into South Africa. This is a serious concern, as special labelling requirements will create a disincentive to bring medical technology to South African patients, clearly an unintended consequence of this labelling requirement. It could also affect the products registration elsewhere and therefore the ability to rely on such registrations. It could also affect sterility, the cost of production and, in the end, the cost of the technology to patients and therefore access to healthcare. This requirement would also disregard the obligations on SAHPRA and medical device companies under Environmental Waste Management legislation.

(ii) SAMED proposes that SAHPRA exclude (or at least minimise) all regulations that require localisation. A special label/Instructions for Use ("IFU") version will add complexity and cost to the supply chain for South Africa, and will potentially result in the closure of medical device businesses or the unavailability of product ranges. This could result in limiting supply of medical devices to South Africa, and loss of access to technology

for patients. Such a requirement would not be rational, as many medical devices are not used by patients or lay persons, and the addition of this information will not add to the safety or performance of any medical device, whilst adding cost and complexity.

(iii) Exclude (or minimise) all regulations that require hard copy. This would also align with waste management requirements. Where appropriate, it may be more practical for users to download electronic labels and IFUs. There is no inclusion of provisions that permit electronic or website labelling to accommodate generally accepted global trends in labelling.

(iv) Minimise the requirements so that it aligns with internationally accepted standards created and recognised by other regulators and the IMDRF. If absolutely necessary, any additional extra requirements on the (electronic) IFU e.g. Authorised Representative.

(m) **Advertising:**

The restrictions on advertising of Class C and Class D medical devices are inappropriate as, unlike medicines, advertisement of medical devices does not promote self-therapy. Lay persons should be able to access information regarding medical technology. The latest amendment proposed to regulation 22(3), namely that Class C and D devices "may be advertised … as determined by the Authority", constitutes an unlawful delegation of legislative power and contains no principles or criteria in terms of which SAHPRA would exercise this power, and for medical device companies to anticipate whether they would, or would not, be subject to an advertisement prohibition.

SAMED strongly proposes that SAHPRA not prohibit any advertisement of any medical device to consumers. The existing regulations have shown how problematic the prohibition is, specifically relating to devices where patients are users, such as glucometers, insulin pumps and equipment used in emergencies, such as defibrillators.

(n) **Animal health.** The scope of regulation of medical devices/IVDs for animal health is not clear.

(o) **Clinical Trials and Clinical Evaluations [Draft Regulation 18]:** – refer also to APPENDIX B

(i) Medical device "clinical evaluations" should also be included – both as a definition and a new provision

(ii) There should be clearer definition of IVD evaluation/investigation terminology and requirements. (Investigation as per ISO14155:2020)
(iii) We recommend that SAHPRA host additional workshops to further define regulations for clinical evaluation, assessment, investigation, trial, exhibition, appraisal, Research Use Only (RUO) of medical devices and IVDs.
(iv) The requirements for clinical trials for Class A and B medical devices are overly burdensome considering that there would also be Ethics Committee oversight, in line with the provisions in the National Health Act, and international approaches to medical device and IVD clinical trials and evaluations should be adopted.

(p) **Appeals and Transitional Measures:**

SAMED welcomes the inclusion of the regulations "Against the decision of the Authority" and "Transitional Arrangements" per our comments submitted on 19 August 2021.

(q) **Quality Management System Certification:**

(i) Many companies who hold a SAHPRA medical device establishment license, do not comply with the ISO 13485 standard, and SAMED welcomes the inclusion of this in the draft regulations. Its implementation may, however, have to be done over time, due to the necessity that all conformity assessment bodies be accredited by SANAS.
(ii) All companies offering ISO 13485 certification services in South Africa should be accredited and should have competence on the South African Medical Device Regulations as well as compliance with ISO/IEC 17021-1.

(r) **Regulations that do not appear in the draft:**

SAHPRA needs to formulate regulations in terms of Section 35(1) of the Medicines Act for the following:
(i) (xxxvi) relating to the scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of medical devices and IVDs;
(ii) (xxxvii) relating to the scientific, pharmaceutical, clinical and other skills required by a member of the council or by a member of the executive committee of the council to evaluate the quality, efficacy and safety of medicines;
(iii) (xliii) relating to time frames for the consideration of applications by the Authority;

(iv) (xlv) generally for the efficient carrying out of the objects and purposes of this Act

Recommendations

A detailed impact analysis assessment should be conducted to identify the impact of the introduction of the amended medical device regulations on the viability of the industry and potential impact on access of medical technologies for patients and users of medical technology i.e. regulations should do no harm.

SAHPRA should also consider adding wholesaling to the scope of a manufacturing and distribution licence. This would eliminate the need for two licences and therefore reduce cost for industry and unnecessary administration for SAHPRA. Manufacturers and distributors already have the required systems for good wholesaling practices in place.

The document which follows indicates to the SAHPRA Board and the Minister where and how the wording of the draft regulations could be changed to address some of the concerns above. SAMED trusts that these comments will be taken into consideration for the final version of the regulations.

SAMED looks forward to constructive engagement with the Department of Health in the future on the matter of appropriate and workable regulations for medical devices and *in-vitro* diagnostics in South Africa.

LEGEND
~~Strikethrough~~ = propose removal
Purple text = propose addition
CAPS = section header
CAPS = section removed from previous regulations (Dec 2016)
Text = industry comment/correction - refers to word or letter in draft regulation
Text = text added per recommendation by industry
✓ = reviewed and accepted without change
× = not accepted

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				It is noted that the references to In Vitro Diagnostic (IVDs) have been removed/edited from these draft regulations.	Recommend including both the definitions and references to IVDs as they are separate in nature to Medical Devices. IVDs are also included in the Medicines Act and require regulations. It is important to differentiate these two as this relates to differences in product classifications, product registrations, references to product listings and establishment license activities in terms of imports and exports, risk management and international norms.
1.	**DEFINITIONS**		**1. DEFINITIONS**		
	In these Regulations a word or expression defined in the Act bears the meaning so assigned and unless the context otherwise indicates-	✓	In these Regulations a word or expression defined in the Act bears the meaning so assigned and unless the context otherwise indicates:-		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
"accessory"	means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use;	✓	means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use;	means an article intended specifically by its manufacturer to be used together with a particular medical device or IVD to enable or assist that device to be used in accordance with its intended use;	Including IVDs as per previous comments on addition of IVDs where applicable.
"adverse event"	~~in relation to a medical device or IVD means possible faults or failures of a medical device or IVD or difficulties in the use of or an undesirable outcome associated with the use of a medical device or IVD that can or does result in permanent impairment, injury or death to the professional user or patient user;~~ means any untoward medical occurrence or undesirable	-include IVD -refer to general comment 5 (j) above -use the EU definition of adverse event (Appendix C)	means any untoward medical occurrence or undesirable incident, that may occur in association with the use of a medical device which—	means any untoward medical occurrence or undesirable incident, that may occur in association with the use of a medical device or IVD which—	Including IVDs as per previous comments on addition of IVDs where applicable.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	incident, that may occur in association with the use of a medical device which				
(a)	does not necessarily have a causal relationship with its use; or		(a) does not necessarily have a causal relationship with its use; or		
(b)	may occur due to its malfunction, its deterioration of safety, quality or performance or an error of its use;		(b) may occur due to its malfunction, its deterioration of safety, quality or performance or an error of its use;		
(c)			(c) can or does result in permanent impairment, injury or death to the professional user or patient user.		The inclusion of elements from the previous definition of adverse events further clarifies potential reportable events. This clarification supports compliance to effective reporting of events that add value to the

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					Authority Post Market Surveillance activities.
~~**"as determined by the council"**~~	~~means as determined by the Medicines Control Council in the guidelines published in the Gazette from time to time;~~	✓			
			"as determined by the Authority" means as determined by the South African Health Products Regulatory Authority (SAHPRA) in a guideline as published from time to time;	✓	
"authorized representative"	means a natural person, resident in the Republic of South Africa, who:		means a natural person, resident in the Republic of South Africa, who—	SAMED stands by its 2021 comment and again proposes the clarification of the definitions. i.e. -refer to general comment 5 (i) above -not harmonized, replace with: **"authorised representative"** means	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				a natural person, resident in the Republic of South Africa, who- (a) has the written mandate to represent a manufacturer or *an appointment from the local distributor* ~~or wholesaler i~~n the Republic; and (b) acts on behalf of a manufacturer, distributor ~~or wholesaler~~, in whose name the licence in terms of section 22C(1)(b) of the Act or certificate of registration is issued; OR authorized representative; natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				regard to the latter's obligations under that country or jurisdiction's legislation [SOURCE: GHTF/SG1/N055:2009, 5.2 Remove reference to ”wholesaler”. Kindly update the definition to align with the IMDRF guidance. Refer to http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.pdf Section 5.2.	
(a)	has the written mandate to represent a manufacturer, ~~importer~~, or distributor	-refer to general comment 5 (b) above -remove “wholesaler”	(a) has the written mandate to represent a manufacturer, distributor or	SAMED stands by previous comment.	Over the past years, the disastrous impact on the medical device supply chain due to the

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~or wholesaler~~, ~~retailer or service provider~~ in the Republic;		wholesaler in the Republic; and		use of medicines as a blueprint has been widely experienced.
(b)	acts on behalf of a manufacturer, ~~importer~~, or distributor ~~or wholesaler~~, ~~retailer or service provider for specified tasks with regard to the latter's obligations and~~ in whose name the ~~manufacturer licence, distributor licence, wholesaler licence~~ licence in terms of section 22C(1)(b) of the Act or certificate of registration is issued; ~~and~~	-refer to general comment 5 (b) above -remove "wholesaler"	(b) acts on behalf of a manufacturer, distributor or wholesaler, in whose name the licence in terms of section 22C(1)(b) of the Act or certificate of registration is issued;	SAMED stands by previous comment.	Medical devices are not supply on a "one s22C-entity, one device" principle, and the supply chain is significantly different.
~~(c)~~	~~is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, Clinical trials or Clinical investigations;~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
"batch number", ~~"lot number" or "serial number" or "'control number" or "version number"~~	means a unique number or combination of numbers or cyphers allocated to a batch or a lot; ~~lot or a batch or a unique medical device or unique accessory to a medical device in the case of "control number", or unique software in the case of "version number" by the manufacturer,~~	✓	means a unique number or combination of numbers, cyphers or letters allocated to a batch or a lot;		
"biological substance"	means a substance derived from a human, animal or a microorganism; **~~"bonded warehouse" means a customs and excise warehouse licensed in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);~~**	✓	means a substance derived from a human, animal or a micro¬organism;		
"bonded warehouse"	means a customs and excise warehouse licensed in terms of section 19 of the	✓	means a customs and excise warehouse licensed in terms of section 19 of the		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	Customs and Excise Act, 1964 (Act No. 91 of 1964);		Customs and Excise Act, 1964 (Act No. 91 of 1964);		
"certification body"	a legal entity that certifies an organisation's quality management system (QMS) ISO13485 in accordance with ISO17021 and is accredited by SANAS or an international body recognised by the Authority.	Added definition - to distinguish from conformity assessment body			
"Chief Executive Officer"	means the Chief Executive Officer of the Authority as appointed in terms of section 3 of the Act;	✓	means the Chief Executive Officer of the Authority as appointed in terms of section 3 of the Act;		
~~**"clinical investigation or**~~ **"clinical trial"**	means a study in or on human or animal subjects undertaken to assess the safety or clinical performance of the medical device; ~~respect of a medical device or IVD for use in humans and animals that involves human or animal subjects and~~	-refer to general comment 5 (o) above	means a study in or on human or animal subjects undertaken to assess the safety or clinical performance of the medical device;	SAMED stands by its previous comments and urge the addition of the various definitions and provisions as per Appendix B.	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~that is intended, through assessment and analysis of the clinical data pertaining to a medical device, to discover or verify the safety· or clinical performance of the medical device or IVD when used as intended by the manufacturer,~~	- include IVD - reinstate clinical investigation, specify only on human subjects, reference standard ISO14155:2020 Clinical investigation of medical devices for human subjects – Good Clinical Practice			
"clinical performance assessment" ~~**study of an IVD"**~~ **performance study**	means a study undertaken to establish or confirm the clinical performance of an IVD or medical device;	-include medical device	means a study undertaken to establish or confirm the clinical performance of an IVD;	means a study undertaken to establish or confirm the analytical or clinical performance of an IVD or medical device	As per EU IVDR that combines elements of IVDs performance including both analytical and clinical
Component				One of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose. A component may be	Definition included to clarify the word as part of SYSTEM introduced later.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				known as a part but not a medical device or IVD in its own right.	
~~**"combination device"**~~	~~means a medical device, incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicine and which is liable to act on the human body with action ancillary to that of the medical device;~~	✓			
"conformity assessment"	means relevant testing, calibration, inspection or certification of a medical device or a quality management system; ~~means the systematic examination of evidence generated and procedures undertaken by the manufacturer, to determine that a medical device or IVD is safe and performs as~~	-replace with IMDRF (GHTF) definition: "the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device or IVD is safe and performs as intended by the	means relevant testing, calibration, inspection or certification of a medical device or a quality management system;	means the systematic examination of evidence generated and procedures undertaken by the manufacturer, to determine that a medical device or IVD is safe and performs as intended and conforms to the Essential Principles of Safety and Performance for Medical Devices as	recommend the IMDRF definition. The conformity assessment body will conduct an analysis of the evidence generated from testing and calibration etc. , but may not necessarily conduct the actual testing and calibration. The conformity assessment must demonstrate

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~intended and that the medical device or IVD fulfils the Essential Principles of Safety and performance for Medical Devices or IVDs, as determined by the Council~~	manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices or IVDs"		determined by the Authority	conformity to a specific quality management system or Essential Principles of Safety and Performance for medical devices and IVDs.
"conformity assessment body"	means a local or international body corporate or other legal entity ~~body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body~~ recognised by the Authority ~~Council~~ as competent to carry out ~~the~~ conformity assessment, ~~verification, inspection testing or certification, as applicable, of medical devices or IVDs, before they are placed on the market by manufacturers, according to criteria~~	-refer to Conformity Assessment Body in terms of product certification -refer to Certification Body (replaces the term Notified Body) in terms of QMS certification	means a local or international body corporate or other legal entity, recognised by the Authority as competent to carry out conformity assessment;	SAMED stands by its previous comment.	To ensure harmonization we recommend that the definitions as published by the IMDRF be adopted. Refer to http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n040-principles-conformity-assessment-050915.pdf

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~determined by the council;~~				
~~**"conformity assessment certificate'**~~	~~means a certificate issued, by a Conformity Assessment Body, to demonstrate compliance with the Essential Principles of Safety and Performance for Medical Device and IVD requirements;~~	✓			
"control number"	means a number or combination of numbers or cyphers allocated to a unique accessory;	✓	means a number or combination of numbers, cyphers or letters allocated to a unique accessory;		
~~**"custom made medical device"**~~ **"medical device that is custom made"**	Means a medical device specifically made in accordance with -	✓	**"custom-made medical device"** means a medical device specifically made in accordance with—		
(a)	~~specifically made in accordance with~~ a written ~~prescription or~~ order given by a person authorized to do so ~~for the same~~ by	✓	(a) a written order given by a person authorised to do so by virtue of his or her professional qualification; and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	virtue of professional qualifications; and				
(b)	~~specifically made in accordance with~~ specific design characteristics;	✓	(b) specific design characteristics,		
~~(c)~~	which is intended for the sole use of a particular user~~;~~ , and	✓	which is intended for the sole use of a particular user, and excludes mass-produced medical devices that only require adaptation to meet the specific requirements of an individual user;		
~~(d)~~	~~which~~ excludes mass produced medical devices that only need adaptation to meet the specific requirements of an individual ~~the health professional~~ user;	✓			
"declaration of conformity"	~~means the procedures whereby the manufacturer ensures and declares that the application of the quality system~~	-clarification that in the case of imported products, the legal manufacturer DoC will be acceptable	means the attestation of the authorised representative of a manufacturer or distributor that the—	Remove reference to the distributor. means the attestation of the authorised representative of a	A declaration of conformity (DoC), as an IMDRF accepted concept, has a fixed technical meaning globally as it is applied

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~approved for the design, manufacture and final inspection of the products concerned, as required by the Council, which are subject to audit and surveillance, are fulfilled;~~ means the attestation of the authorized representative (or in the case of an imported product, the attestation of the legal manufacturer) of a manufacturer or distributor that the-	- reference http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n40-2006-guidance-ca-principles-060626.pdf , section 5.2.2		manufacturer that the—	by manufacturers and certified against such known and internationally accepted principles. For local and multinational companies in South Africa, their devices and sites need to be internationally aligned and evaluated by similar criteria, so as to ensure global consistency as a measure of quality. It would therefore be important to remove references to the distributor since the attestation in the DOC

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					is the **responsibility of the manufacturer.** It is also the authorised representative of the legal manufacturer that attests to the conformity, and in a South African context this is not necessarily the same as the Authorised Representative for the establishment license to "manufacture, import or distribute".
(a)	relevant quality management systems fulfil requirements as determined by the Authority; and	✓	(a) relevant quality management systems fulfil requirements as determined by the Authority; and		
(b)	medical devices concerned fulfil the essential principles;	✓	(b) medical devices concerned fulfil the essential principles;	medical devices and IVDs concerned fulfil the essential principles;	inclusion of IVDs
"distribute"	means to -				
(a)	Import, purchase or export a medical device in its final form,	-refer to general comment 5 (i) above regarding clarification of economic operators			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	wrapping and packaging; and/or	in medical device supply chain			
(b)	sell the medical device to any person other than a manufacturer or distributor;				
"distributor"	means a ~~natural or legal~~ person ~~who~~ licensed to distribute ~~and or wholesale~~ medical devices in terms of section 22C(1)(b) of the Act;	- refer to general comment 5 (b) and (i) above -wholesale taken out -definition could be 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service	means a person licensed in terms of section 22C(1)(b) of the Act to import or export a medical device in its final form, wrapping and packaging and sell such medical device to a person other than a manufacturer or distributor;	means a person licensed to distribute medical devices and IVDs in terms of section 22C(1)(b) of the Act to import or export a medical device or IVD in its final form, wrapping and packaging and sell the medical device or IVD to any person other than a manufacturer or distributor or to further the availability of a medical device or IVD to the end user.	Inclusion of IVDs. This definition is in line with the GHTF definition. It includes the possibility that more than one distributor may be involved in the supply chain, and excludes logistics providers, i.e. persons involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor. In some cases a distributor may import a medical device or IVD which could be sold to a manufacturer as a further part or component or

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					procedure pack. The supply chain for medical devices and IVDs could include the sale of a medical device or IVD from a distributor to another distributor who could be assigned to export the medical device or IVD as part of a collective export tender or onward selling into Africa. Therefore recommend not to limit the sale of Medical Devices and IVD onward sale to only wholesalers, end users or retail only.
~~(a)~~	~~imports or exports a medical device or IVD, which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to the medical device or IVD being~~	- import, [~~procure~~] place on the South African market or export a medical device ~~in its final form, wrapping and packaging; and/or~~ *(note that a manufacture license includes distribution)*			The distributor is not only the person, but also a company. 'any natural or legal person'

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~placed on the market under the natural or legal person's own name; and~~				
~~(b)~~	~~sells the medical device or IVD to a healthcare professional, healthcare institution, wholesaler or the user;~~				
"essential principles"	means the requirements relating to the safety and performance characteristics of medical devices and IVDs determined by the Authority ~~Council~~;	✓	means the requirements relating to the safety and performance characteristics of medical devices as determined by the Authority;	means the requirements relating to the safety and performance characteristics of medical devices or IVDs as determined by the Authority;	inclusion of IVDs
"expiry date"	means the date up to which a medical device ~~or IVD~~ retains the properties stated ~~which are mentioned~~ on the label, which properties can change after the lapse of time, and after which date the medical device ~~or IVD~~ may not be sold to the public or used;	-include IVDs Alternative definition: - the date until which the device may safely be used (i.e. put into service), expressed as the year and month (e.g. on single-use disposable devices) where this is relevant (ref. GHTF SG1-N009R6-Labelling)	means the date up to which a medical device retains the properties stated on the label, which properties can change after the lapse of time, and after which date the medical device may not be sold to the public or used;	means the date up to which a medical device or IVD retains the properties stated on the label, which properties can change after the lapse of time, and after which date the medical device or IVD may not be sold to the public or used;	inclusion of IVDs

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
"family"	means a medical device ~~or IVD~~ comprising of the same type of medical device available in different models and sizes;	✓ -include IVDs	means medical devices or IVDs that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use, and excludes a group;		
"group"	means a medical device ~~or IVD~~ comprising a collection of medical devices ~~or IVDs~~ such as a procedure pack, procedure tray, system procedure or IVD ~~procedure~~ kit, that are packaged together for a specific intended purpose and sold under a single name;	✓	means a medical device comprising a collection of medical devices such as a procedure pack, procedure tray, system, procedure or IVD kit, that are packaged together for a specific intended purpose and sold under a single name;	means a medical device or IVD comprising a collection of medical devices such as a procedure pack, procedure tray, system, procedure or IVD kit, that are packaged together for a specific intended purpose and sold under a single name;	inclusion of IVDs
"health care provider"	means a health care provider as defined in section 1 of the National Health Act,	✓	means a health care provider as defined in section 1 of the National Health Act,		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	2003 (Act No. 61 of 2003);		2003 (Act No. 61 of 2003);		
"health establishment"	means a health establishment as defined in section 1 of the National Health Act, 2003 {Act No. 61 of 2003);	✓	means a health establishment as defined in section 1 of the National Health Act, 2003 (Act No. 61 of 2003);		
"holder of a certificate of registration"	means a manufacturer or distributor ~~person~~ in whose name a registration certificate has been granted and who is responsible for all aspects of the medical device ~~or IVD~~, including performance, quality, safety and compliance with conditions of registration;	-refer to general comment 5 (i) above - foreign manufacturers should also be held as holders of certificates of registration means a SAHPRA S22C licensed manufacturer or distributor ~~person in whose name a registration certificate~~ who makes application for the registration of the product and is granted a certificate in compliance with conditions of registration and the regulations;	means a manufacturer or distributor in whose name a certificate of registration for a medical device has been granted and who is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration;	means a manufacturer or distributor in whose name a certificate of registration for a medical device or IVD has been granted and who is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration	inclusion of IVDs

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		note the AR is responsible for safety and quality etc			
~~**"identification number"**~~	~~means the number drawn from a~~	✗ - not needed and not appropriate for publication (ref. POPI Act)	**"identification number"** means the number drawn from a—	✗ - not needed and not appropriate for publication (ref. POPI Act)	
~~(a)~~	~~birth certificate, passport, valid driver's licence;~~		(a) birth certificate, passport, valid driver's licence; (b) South African identification document; or any other relevant document issued by the Department of Home Affairs;		
~~(b)~~	~~South African identification document; or~~				
~~(c)~~	~~any other relevant document issued by the Department of Home Affairs;~~				
"implantable device"	means a medical device, which is intended to- ~~including a medical device that is~~	✓	means a medical device, which is intended to—		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~partially or wholly absorbed, which -~~				
(a)	~~is intended to~~ be totally introduced into the ~~human~~ body or, to ~~replace an epithelial surface~~ ~~or~~ the surface of the eye by surgical intervention; and	✓	(a) be totally introduced into the body;		
(b)	Be partially introduced into the body through surgical intervention and ~~is~~ intended to remain in place after the procedure for at least 30 days ~~after the procedure~~;	✓	(b) be partially introduced into the body through surgical intervention and intended to remain in place after the procedure for at least 30 days;		
(c)	replace an epithelial surface; or	✓	(c) replace an epithelial surface; or		
(d)	replace the surface of the eye by surgical intervention,	✓	(d) replace the surface of the eye by surgical intervention, and includes a medical device that is partially or wholly absorbed by the body;		
"importer"	means any person established within South Africa that delivers or supplies	Added definition			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	within the Republic for dispatch to any destination outside the Republic				
"Instructions for use"			means general and technical information to inform the user of the medical device's intended purpose, proper use and of any contra-indications, warnings or precautions to be taken, as provided for in regulations 7 and 8, written in a manner which is easy for the end user to understand;		
"intended purpose"	means the objective, or use for which a medical device ~~intended use or purpose, as the case may be, for which a medical device or IVD~~ is intended according to the data supplied by the manufacturer or	✓ or: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer	means the objective, or use for which a medical device is intended according to the data supplied by the manufacturer or distributor and approved by the Authority;	Remove reference to distributor. means the objective, or use for which a medical device or IVD is intended according to the data supplied by the legal manufacturer	means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as

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	distributor (as per data received from original manufacturer) and approved by the Authority. ~~authorised representative on the labelling, in the instructions for use and in the promotional materials;~~	Note: It is wholly inappropriate for the distributor to determine an intended use. They may share the intended use as it is determined by the manufacturer, but distributors cannot determine intended use			specified by the manufacturer in the performance evaluation (Reference to the EU MDR and IVDR) Include IVDs.
"ISO 13485"	means the International Standard "Medical devices – Quality management systems - Requirements for regulatory purposes"; reference number ISO 13485;	✓ means the International Standard "Medical devices – Quality management systems - Requirements for regulatory purposes"; reference number ISO 13485, and includes SANS13485;	means the International Standard "Medical devices — Quality management systems — Requirements for regulatory purposes"; reference number ISO 13485;		
label				means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices and	Addition of definition

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				which may be accessible by electronic means	
"maintain"	means the-	✓ - replace the term "maintain" with the term "service" – "maintain" is an internal term in ISO13485 -include IVDs	means the—		Add a definition of "listing" [e.g. "means the entry of specific details relating to class A [and B?] medical devices and IVDs on a register containing ….]
(a)	service, repair and re-establishment of the function; or	✓	(a) service, repair and re-establishment of the function; or		
(b)	update of software or hardware,	✓	(b) update of software or hardware,		
	of a medical device without significantly changing the performance or safety characteristics of a medical device; and "maintenance" has corresponding meanings;	✓	of a medical device without significantly changing the performance. or safety characteristics of a medical device; and "maintenance" has corresponding meanings;	of a medical device or IVD without significantly changing the performance. or safety characteristics of a medical device or IVD; and "maintenance" has corresponding meanings;	
~~**"IVD"** ("in-vitro diagnostic")~~	~~means a medical device, whether used alone or in combination, intended~~	-definition is in Act 101, no need to repeat in the Regulations			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;~~				
~~**"lay person"**~~	~~means a person who does not have formal training in a relevant field or discipline;~~	✓			
"legal manufacturer"	"**[**~~original~~**]** **Legal** manufacturer " means the **[**~~manufacturer responsible for the~~**]** **natural or legal person with legal authority to** design **[**~~and specification development of a medical device~~**]** **, manufacture, package and label a device before it is placed on the market, regardless of whether these**	Added definition Alternative definition: MDR, FDA and IVDR does NOT define a legal manufacturer FDA: "Manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name,			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	operations are carried out by that person himself or on his behalf by a third party and in whose name a registration certificate has been granted and who is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration;	regardless of whether these operations are carried out by that person himself or on his behalf by a third party."			
"manufacture"	means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, ~~reprocessing, releasing~~, packaging, repackaging, labelling, releasing, installation, maintaining, reprocessing or ~~and~~ refurbishing of a	-means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, releasing, packaging, repackaging, labelling, releasing, installation, maintaining, reprocessing or refurbishing of a medical device or IVD,	means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, releasing, installation, maintaining, reprocessing or refurbishing of a medical device, and includes the assembly	Remove reference to maintaining means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, releasing, installation, reprocessing or refurbishing of a	The act of instrument maintenance or servicing is an integral activity to the operations of IVD instrumentation on a regular basis and may not necessarily be a manufacturing function. If this term remains in the definition of "manufacture" then this could imply that the laboratories

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	medical device ~~or IVD~~, ~~as the case may be,~~ and includes the assembly of a ~~putting a~~ collection of medical devices ~~or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls;~~	~~as the case may be,~~ and includes procedure and system packs ~~the assembly of a putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls~~; (note: in line with the activities / types in classification rules i.e. procedure and system packs and reprocess and refurbish have legal manufacturer obligations and QA and QC are activities of release)	of a collection of medical devices;	medical device or IVD, and includes the assembly of a collection of medical devices	undertake a manufacturing function if maintenance was part of the manufacture definition. The scope of "maintain" is well defined in the definition of "maintain" in the proposed regulations.
"manufacturer"	means a person licensed to manufacture, import, distribute, export ~~or~~ ~~wholesale~~ medical devices in terms of	means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and	means a person licensed in terms of section 22C(1)(b) of the Act to manufacture, import or export a medical device and sell such	means a person licensed in terms of section 22C(1)(b) of the Act to manufacture, import or export a medical device or IVD and sell	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	section 22C(1)(b) of the Act;	markets that device under its name or trade mark ~~[and who is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration];~~ *(these are part of manufacture definition)* ~~regardless of whether these operations are carried out by that person himself or on his behalf by a third party~~ *(these are covered in the QMS ISO13485)* For reference, the TGA definition: Manufacturer - Corporation or person carrying out one or more of the steps specified in the definition of manufacture	medical device to a licenced wholesaler or end user;	such medical device or IVD to a licenced wholesaler or end user;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		Manufacturer of a medical device - The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations. If subsection (1) does not apply to a medical device, the manufacturer of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready-made products:			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		assembles the device; packages the device; processes the device; fully refurbishes the device; labels the device; assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following: the labelling on the device; the instructions for using the device; any advertising material relating to the device. However, a person is **not the manufacturer** of a medical device if: -the person assembles or adapts the device for an individual patient; and -the device has already been supplied by another person; and			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		-the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following *(aka a distributed by label)* : the labelling on the device; the instructions for using the device; any advertising material relating to the device. Or: Align definition of manufacturer with ISO 13485 **Manufacturer** natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).			
~~(a)~~	~~a natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried cut by that person by himself or on his or her behalf by a third party; or~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(b)~~	~~any other person who assembles, packages, reprocesses, refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD, . with a view to their being placed on the market under the natural or legal person's own name, except a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;~~				
"medical device or IVD establishment"		Refers to the definition in the Act as amended by Act 72 of 2008 and: a) does not include pharmacy wholesaler or exporter b) includes service provider and retailer that is not defined			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		c) separates importer from distributor note: importer is not defined in the Act and exporter is not defined in Regs Export is defined in Act 101, not regulations. **"Export"** includes delivery or supply within the Republic for dispatch to any destination outside the Republic; [Definition of "export" inserted by s. 1 (*a*) of Act No. 17 of 1979.]" The definition in the Act cannot be amended by regulation.			
"model"	means a number or combination of numbers or cyphers allocated to a medical device;	✓	means a number or combination of numbers, cyphers or letters allocated to a medical device;	means a number or combination of numbers, cyphers or letters allocated to medical device or IVD	Inclusion of IVDs
~~**"misbranded"**~~	~~means a medical device labelling is false,~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~misleading, inaccurate or fails to provide information as required;~~				
"modification"	in relation to a medical device ~~or IVD~~ means -	It is important to align on the correct definition. Only significant changes impacting the intended use, safety or effectiveness, or that increase the classification of a device should need regulatory approval (or reliance on another regulators' approval). All other changes should not need SAHPRA approval before introduction. Regulation that requires regulators' approval for every change to production, labelling or raw material is not workable. Changes in expiration dates and labelling should also	in relation to a medical device means—	in relation to a medical device or IVD means—	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		not require regulator's approval as long as the minimum shelf life has been maintained. Loss of shelf life waiting for approval must be avoided.			
~~(a)~~	~~any significant change in a medical device or IVD;~~		(a) any change in the purpose and the intended use of a medical device;	(a) any change in the purpose and the intended use of a medical device or IVD;	
(b)(a)	any change in the purpose of a medical device ~~or IVD~~, where significant change may relate to ~~include~~				
(i)	the manufacturing process				
(ii)	facility or equipment				
(iii)	the quality control measures used to control the quality and sterility of a medical device ~~or IVD;~~ or				
(iv)	a change of the materials used in manufacture~~, the design~~ of a medical device ~~or IVD,~~ ,the				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	design of a medical device including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories and the intended use of a medical device ~~or IVD~~;				
(v)	Any change to the method or process of sterilisation of the medical device	-consider additional aspect of definition of "modification"			
(b)	any significant change in the safety profile or specifications of a medical device as determined by the Authority		(b) any significant change in the safety profile or specifications of a medical device as determined by the Authority;	Any significant change in the safety profile or specifications of a medical device or IVD as determined by the Authority;	
(c)	any new or extended use, any addition or deletion of a contra-indication of a medical device ~~or IVD; and~~ ;or		(c) a change in the materials used in manufacture of a medical device, the design of a medical device, including its performance characteristics,	a change in the materials used in manufacture of a medical device or IVD, the design of a medical device or IVD, including its performance characteristics,	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			principles of operation and specifications of materials, energy source, software or accessories;	principles of operation and specifications of materials, energy source, software or accessories;	
(d)	any change to the period used to establish the ~~its~~ expiry date of a medical device;		(d) any new or extended use of a medical device;		
(e)			(e) any addition or deletion of a contra-indication of a medical device; or		
(f)			(f) any change to the period used to establish the expiry date of a medical device		
(g)			(g) where significant change may relate to-		
(i)			(i) the manufacturing process;		
(ii)			(ii) the facility or equipment; and		
(iii)			(iii) the quality control measures used to control the quality and sterility of a medical	the quality control measures used to control the quality and sterility of a medical device or IVD;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			device; the manufacturing process;		
~~**"near patient testing"** or **"point of care testing"**~~	~~means testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, a patient;~~				
"nomenclature system code"	means the code linked to the common generic description as per the Global Medical Device Nomenclature (GMDN) for medical devices having similar features, characteristics and intended use;	✓	means the code linked to the common generic description as per the Global Medical Device Nomenclature (GMDN) for medical devices having similar features, characteristics and intended use;		
~~**"original manufacturer"**~~	~~means the manufacturer responsible for the design and specification development of a medical device;~~	-replace with "legal manufacturer"	**"original manufacturer"** means the manufacturer responsible for the design and specification	**"~~original manufacturer"~~ "Legal** manufacturer " means the **[**~~manufacturer responsible for the~~**]** **natural or legal person with legal authority to** design **[**~~and~~	: We recommend replacing original manufacturer with the legal manufacturer definition to ensure alignment with IMDRF principles.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			development of a medical device;	~~specification development of a medical device~~] **, manufacture, package and label a device before it is placed on the market, regardless of whether these operations are carried out by that person himself or on his behalf by a third party and in whose name a registration certificate has been granted and who is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration**	
''on the market"	'on the market' means the first making available of a device, other than a device for performance study, on the South African market;	-added definition			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~**"near patient testing"**~~ ~~or~~ **"point of care testing"**	means testing performed outside a laboratory environment by a healthcare provider; ~~professional not necessarily a laboratory professional, generally near to, or at the side of, a patient;~~	✓	means testing performed outside a laboratory environment by a health care provider or veterinarian; and includes near patient testing;	means testing performed outside a laboratory environment by a health care provider or veterinarian; and includes near patient testing or lay person and is dependent on the intended purpose of the IVD.	. Point of care testing could also include the use of IVDs by the lay person.
"radiation"	means ~~energy in the form of electromagnetic waves or acoustical waves;~~	✓	means—		
(a)	electromagnetic or particle radiation capable of producing ions, directly or indirectly, while passing through matter; or	✓	(a) electromagnetic or particle radiation capable of producing ions, directly or indirectly, while passing through matter; or		
(b)	energy in the form of electromagnetic waves or acoustical waves;	✓	(b) energy in the form of electromagnetic waves or acoustic waves;		
"refurbish"	means the substantial rebuilding, re-equipping, reworking	Software modifications are not refurbishing	means the substantial rebuilding, re-equipping, reworking		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	or restoring of the whole or part of a medical device~~,~~ ~~including the substantial updating or modification of software or hardware~~, which does not significantly change the performance, safety specifications and intended purpose of the medical device; ~~in relation to a medical device or IVD means the whole or part of a medical device or IVD is substantially rebuilt, re-equipped, reworked or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device or IVD that is used for the purpose originally intended by the original manufacturer of the original medical~~		or restoring of the whole or part of a medical device, including the substantial updating or modification of software or hardware, which does not significantly change the performance, safety specifications and intended purpose of the medical device;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~device or IVD and without prejudice to the generality of the foregoing, refurbishment of a medical device may involve any or all of the following actions; including, but not limited to, repair, rework, update of software or hardware and replacement of worn parts with parts approved for use by the original manufacturer, performed in a manner consistent with product specifications and service procedures defined by the original manufacturer for that type of equipment. without significantly changing the finished equipment's performance, safety specifications or intended use as~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~defined in its original registration;~~				
"research use only ~~IVD~~"	("RUO ~~IVD~~") means in the case of an IVD ~~labelled for "research use only" and "for investigational use only" and~~ that which is intended only for research or investigational use and which may not be used for clinical diagnostic purposes;	-include medical devices -refer to general comment 5 (k) and (o) above	("RUO") means an IVD which is intended only for research or investigational use and which may not be used for clinical diagnostic purposes;	Include medical devices	
"reprocess"	means the act of following validated reprocessing instructions ~~activity~~ carried out on a used medical device in order to allow its safe re-use including cleaning, disinfection, sterilization and related procedures, as well as testing and restoration of the technical and functional safety of the ~~used~~ medical device;		means the activity carried out on a used medical device to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the medical device;	means the activity carried out on a used medical device or IVD to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the medical device or IVD;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
"SANAS"	means the South African National Accreditation System (SANAS) established by section 3 of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act No.19 of 2006);	✓	means the South African National Accreditation System (SANAS) established by section 3 of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act No.19 of 2006);		
"SANS 10386"	means the South African National Standard "The care and use of animals for scientific purposes", reference number SANS 10386;	✓	means the South African National Standard "The care and use of animals for scientific purpose", reference number SANS 10386;		
"serial number"	means a unique number or combination of numbers or cyphers allocated to a unique medical device or unique accessory to a medical device;	✓ include IVDs	means a unique number or combination of numbers, cyphers or letters allocated to a unique medical device or unique accessory to a medical device;	means a unique number or combination of numbers, cyphers or letters allocated to a unique medical device or unique accessory to a medical device or IVD;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~**"self-testing"**~~	~~means testing performed by a lay person;~~				
"single-use"	~~in terms of a medical device~~ means one use of - ~~a medical device on an individual or IVD on a sample during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again;~~	✓	means one use of—		
(a)	of a medical device on an individual ; or	✓	(a) a medical device on or by an individual; or		
(b)	an IVD on a sample	✓	(b) an 1VD on a sample;		
system				refers to a medical including an in IVD, that is sold under a single name and contains a number of COMPONENTS by the same manufacaurer intended to be used together to fulfil some or all of the device's intended functions.	All the components of the SYSTEM that are produced by the MANUFACTURER of the SYSTEM are deemed licensed when the SYSTEM is licensed.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
"the Act"	means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);	✓	means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);		
"user"	means a person or organisation that uses a medical device ~~or IVD; and~~	✓ include IVDs	means a person or organisation that uses a medical device;	means a person or organisation that uses a medical device or IVD;	
"version number"	means a number or combination of numbers or cyphers allocated to unique software; and	✓ not limited to SW	means a number or combination of numbers, cyphers or letters allocated to unique medical device software; and		
"wholesaler"	means a ~~dealer~~ person, other than a manufacturer or distributor who purchases medical devices ~~or IVDs~~ from a manufacturer or distributor and sells them in terms of section 22H of the Act. ~~to a retailer.~~ Or: use this definition **"wholesaler"** including a wholesale pharmacy means a person who holds, stores, delivers	-refer to general comment 5 (b) above In order to reduce unnecessary complexity and avoid unintended consequences, there should be **no separate license for wholesaler.** Or: Wholesaler should apply to establishments that handle **medicines only** that meet the	means a person licensed in terms of section 22C(1)(b) of the Act to purchase a medical device from a manufacturer or a distributor, licensed in terms of section 22C(1)(b) of the Act, and sells such medical device as per section 22H of the Act.	Wholesaler not applicable to medical devices	SAMED acknowledges that sections 22C and 22H may require amendment, but experience has shown that this provision is causing numerous issues, leading to unfair results, where entities cannot lawfully sell and healthcare providers are deemed to be wholesalers, etc.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	or purchases medicines or Scheduled substances from a manufacturer and sells them in terms of section 22H of the Act and GN 859 of 25 August 2017: General Regulations (Government Gazette No. 41064)	definition in the General Regulations			
2.	**Manner and conditions for allowing international tendering**	-refer to general comment 5 (h) above. The empowering section in the Act does not apply to medical devices or IVDs			
(1)	The State may tender for a medical device or IVD internationally if the medical device ~~or IVD~~	Delete			
(a)	can be obtained at a lower price outside of the Republic; or	Delete			
(b)	is, in the opinion of the Minister, essential for national health.	Delete			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(2)	~~A medical device or IVD may not be procured by international tender unless the medical device or IVD is registered.~~ A medical device subject to registration in terms of section 14(2) of the Act may not be procured by international tender, unless the medical device is registered in terms of the Act	Delete			
3.	**Importation of medical devices ~~and IVDs Into the~~ Republic**	SADC issue: to be resolved via multilateral consultation and harmonization initiatives	**2. Importation of medical devices into Republic**		
(1)	A person may not import a medical device ~~or IVD~~ into the Republic except through one of the		(1) A person may not import a medical device into the Republic except		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	following ports of entry:		through one of the following ports of entry:		
(a)	Cape Town International Airport or harbour.		(a) Cape Town International Airport or harbour;		
(b)	Port Elizabeth Airport or harbour,		(b) Chief Dawid Stuurman International or Port Elizabeth harbour;		
(c)	King Shaka International Airport or Durban harbour, or		(c) King Shaka International Airport or Durban harbour; or		
(d)	OR Tambo International Airport.		(d) OR Tambo International Airport.		
(2)	~~Despite sub-regulation 3(1),~~ used medical devices, ~~or IVDs~~ other than a medical device designated by the ~~original~~ legal manufacturer or as determined by the Authority for single use only may be imported by a licensed manufacturer for purposes of service, repair, refurbishing or maintenance	Include recommended text/deletion 'Original' manufacturer is the term used in s22H in the Act. It cannot be changed through a regulation.	(2) A used medical device, other than a medical device designated by the original manufacturer or as determined by the Authority for single use only, may be imported by a manufacturer for purposes of refurbishing or maintenance through ports of entry, as determined by the		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			Authority, other than those stipulated in sub-regulation (1).		
(3)	A person may only import a medical device ~~or IVD~~ if that person-	✓	(3) A person may only import a medical device if that person—		
(a)	is licensed in terms of section 22C(1)(b) of the Act to import medical devices or ~~IVDs;~~ and	✓	(a) is licensed in terms of section 22C(1)(b) of the Act to import a medical device; and		
(b)	In the case of an unregistered medical ~~devices~~ device ~~or IVDs,~~ is authorised by the ~~Council~~ Authority to import the unregistered medical device~~s or IVDs~~.	✓	(b) in the case of an unregistered medical device, is authorised by the Authority to import such unregistered medical device.		
4.	**Transmission of medical devices ~~or IVDs~~ through ~~the~~ Republic**		**3. Transmission of medical devices through Republic**		
(1)	Medical devices ~~and IVDs~~ that are transmitted through the Republic must-		(1) A medical device that is transmitted through the Republic must—		
(a)	while stored in the Republic, be stored in a	✓	(a) while stored in the Republic, be stored in a		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	bonded warehouse which is ~~registered with the Council;~~ licensed in terms of section 22C(1)(b) by the Authority to import or export medical devices;~~-~~and		bonded warehouse which is licensed in terms of section 22C(1)(b) by the Authority to import or export medical devices; and		
(b)	not be manipulated while in the bonded warehouse unless authorised by the ~~Council~~ Authority.	-consider labelling activities	(b) not be manipulated while in the bonded warehouse unless authorised by the Authority.		
(2)	A bonded warehouse referred to in sub-regulation (1) must comply with ~~the specified storage conditions determined by the Council.~~		(2) A bonded warehouse referred to in sub-regulation (1) must comply		
(a)	good distribution practice; and	✓ ISO 13485 service controls	(a) good distribution practice; and		
(b)	license conditions as determined by the Authority	✓	(b) licence conditions as determined by the Authority.		
~~11.~~ 5.	**Classification of medical devices ~~and IVDs~~**	-refer to general comment 5 (d) above	**4. Classification of medical devices**		
(1)	~~The following are the classes of medical~~	-include IVDs	(1) Medical devices are classified by the		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~devices and IVDs:~~ Medical devices are classified by the Authority into the following classes:		Authority into the following classes:		
(a)	Class A – Low Risk		(a) Class A – Low Risk;		
(b)	Class B – Low-moderate Risk		(b) Class B – Low-moderate Risk;		
(c)	Class C – Moderate-high Risk		(c) Class C – Moderate-high Risk; and		
(d)	Class D – High Risk		(d) Class D – High Risk		
	~~where risk relates to the patient user or to public health.~~	-reinstate "where risk relates to the patient, user or to public health", which defines the type of risk for which Classification was designed	where the risk relates to the patient, user or to public health.		
(2)	~~Medical devices, except custom made medical devices, and IVDs must be registered with the Council in terms of call up notices before they may be sold or used in the Republic.~~ The Authority may determine the classification rules in	-regulation through guidelines is not permitted. -classification should harmonize wherever possible. To clarify: Guidelines cannot CREATE law or legally binding provisions but flow	(2) The Authority must determine the classification rules in guidelines published from time to time.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	guidelines published from time to time.	from, or give flesh to principles of law.			
(3)	~~The Council must determine the classification of medical devices and IVDs~~ The Authority may classify a medical device in accordance with the classification rules as determined by the authority.	× Delete (3): This is a major problem for imported goods, which would need re-certification for South Africa, incurring costs which will be prohibitive for access to South African public. The basis of classification is rules for intended use, not as a tool for restriction of supply (i.e. not the same as scheduling of medicines for pharmacist control).	(3) The manufacturer or importer must classify a medical device in accordance with the classification rules as determined by the Authority.	Manufacturer classification of imported products should be accepted in SA	
~~(4)~~	~~Where the classification of a medical device or IVD is inconclusive and places it in more than one class, or between classes, the Council must, after following the classification rules,~~	The absence of rules such as these make the Guidelines less and less connected to the Regs, and more susceptible to creating, and not giving effect to, law. This then becomes and unauthorized	(4) Where the classification of a medical device is inconclusive and places it in more than one class, or between classes, the Authority must place the medical		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~place the medical device or IVD in the higher of the risk classes.~~	delegation of legislative authority.	device in the higher of the risk classes.		
~~(5)~~	~~The Council must consider the classification of a medical device or IVD individually, taking into account its design and intended use.~~				
~~22.~~ 6.	**Labelling of medical device~~s or IVD~~**	-include IVDs -refer to general comment 5 (I) above	**5. Labelling of medical devices**		
~~(2)~~(1)	The label of each medical device ~~or IVD~~ must be in at least English and shall take the form of international symbols in accordance with ISO 15223-1 and must appear -		(1) The label of each medical device must be in at least English and must appear—	The label of each medical device or IVD be in at least English and must appear—	
(a)	on the medical device ~~or IVD~~ itself, or on the packaging thereof or in electronic form; and		(a) on the medical device itself or on the packaging thereof; and	on the medical device or IVD itself or on the packaging thereof; whether in electronic	SAMED recommends the inclusion of electronic format of labels especially for smaller devices as is

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				format or otherwise and : 1) The label of each medical device must be in at least English and must appear- (a) on the medical device itself or on the packaging thereof **or in electronic format**; and	the norm internationally.
~~(b)~~	~~on the packaging of each unit; and~~				
~~(c)~~ (b)	on the packaging of multiple medical devices ~~or IVDs~~ or in electronic form		(b) on the packaging of multiple medical devices.	on the packaging of multiple medical devices or IVDs.	
~~(1)~~ (2)	The label of each medical device ~~or IVD~~ must contain the following particulars:		(2) The label of each medical device must contain the following particulars:	(2) The label of each medical device or IVD must contain the following particulars:	
(a)	The proprietary name, and where applicable, the model ~~or trade name~~ of the medical device ~~or IVD~~;	-include trade name	(a) the proprietary name and, where applicable, the model of the medical device;	(a) the proprietary name and, where applicable, the model of the medical device or IVD;	
(b)	product description and intended use;		(b) product description and intended use;	Where applicable some products very small	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(c)	~~a product catalogue code, where applicable; the registration number of the medical device allocated in terms of section 15(5) of the Act;~~	× - not international best practice - legal manufacturer should be registered	(c) the registration number of the medical device allocated in terms of section 15(5) of the Act;	Not feasible on all products labels Delete ~~(c) the registration number of the medical device allocated in terms of section 15(5) of the Act;~~ :	SAMED recommends deletion of this requirement on the primary and secondary labels as most medical devices and IVDs have shared packs with other countries to ensure efficiency in manufacturing process. If this requirement is retained, it will result in local re-labelling to be done which will compromise the final finished product and place further resource burden on applicants. Refer to our motivation included in the executive summary of our comments document. Also refer to the IMDRF guidance on labelling[1].

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					[1] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf
(d)	~~the name and business address of the manufacturer~~ ~~holder of a licence as per regulation 13(1)(a)(i) or 13(1)(a)(ii), where applicable;~~	× may be included on electronic IFU	(d) the name and physical address of the holder of a licence as per regulation 12(1)(a)(i) or 12(1)(a)(ii), where applicable;	Not feasible on all labels Delete : ~~d) the name and physical address of the holder of a licence as per regulation 12(1)(a)(i) or 12(1)(a)(ii), where applicable;~~	This information can be supplied in the invoice/accompanying documentation. To ensure supply of MD and IVD-products and also the fast availability of innovative products to the patients in South Africa, we recommend sticking to common requirements for labels and IFU, as laid down in IMDRF/GRRP

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					WG/N52 FINAL:2019 (see chapters 5 and7). We recommend for your consideration exclusion of these requirements. Current practices within other jurisdictions globally require only the manufacturer's name and address on the primary and secondary labels, but not the local company's name and address. Further supporting references can be found below:

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					Justifications/ Reasons for Exclusion: 1.The local distributor or manufacturer facility licenses in South Africa list the medical device products which are distributed within the country as is provided in the license application and this information should be readily available on the SAHPRA Medical Device Register. 2.The name and business address of the legal manufacturer appears on the medical device and complies to current Regulation 22(1)(d).

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					3.Adding the local address to the packaging might impact the safety and quality of the device by means of having to break the original packaging and removing the product and its components from the primary packaging, which is a detrimental step especially for sterile products. Tampering with a medical device packaging potentially increases product and patient risk.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					4.In case of adverse events, these are reported to the Authorised Representatives or directly to the company. In most instances details on the order records or invoices are used to notify the appropriate local representative. 5.Track and trace can also be determined by the UDI 6. In a clinical setting it is unlikely that a surgeon would keep the packaging of a

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					medical device for reference. 7.The increased lead-time for generation of new artwork and acquiring local and global approval will significantly impact customer service and overall product availability in South Africa.
(e)	the name and business address of the holder of the certificate of registration;	× may be included on electronic IFU This information can be supplied in the invoice as per reference to the EU Regs, Article 13.3 (see below). Recommend for your consideration exclusion of these requirements. Current practices within other jurisdictions globally require only the legal	(e) the name and physical address of the holder of the certificate of registration;	Delete : ~~e) the name and physical address of the holder of the certificate of registration;~~	: SAMED recommends that SAHPRA Embrace digital labels. Current labelling regulations differ across countries and create significant logistical challenges, especially during device shortages. As a result, devices can only

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		manufacturer name and address on the primary and secondary labels, but not the local company's name and address. <u>Justifications/ Reasons for Exclusion:</u> 1.The local distributor or manufacturer facility licenses in South Africa list the medical device products which are distributed within the country as is provided in the license application and this information should be readily available on the SAHPRA Medical Device Register. 2.The name and business address of the legal manufacturer appears on the medical device and complies to			be used in their intended market due to localized labelling requirements. In addition to electronic IFUs, digital labels can provide additional information beyond what is printed on the device. Industry agrees that core information on the identification of a device and handling are needed, nevertheless we encourage a regulatory framework to enable additional information, especially information from country-specific

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		current Regulation 22(1)(d). 3.Adding the local address to the packaging might impact the safety and quality of the device by means of having to break the original packaging and removing the product and its components from the primary packaging, which is a detrimental step especially for sterile products. Tampering with a medical device packaging potentially increases product and patient risk. 4.In case of adverse events, these are reported to the Authorised Representatives or directly to the company. In most			regulations, to be made available to users via a digital label. Adoption of digital labels can improve the user experience. Additionally, digital labels allow manufacturers to reduce the need for printing and packaging, leading to environmental benefit. And even while we move towards digital labelling, the opportunity to have both a physical and digital label.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		instances details on the order records or invoices are used to notify the appropriate local representative. 5.Track and trace can also be determined by the UDI 6. In a clinical setting it is unlikely that a surgeon would keep the packaging of a medical device for reference. 7.The increased lead-time for generation of new artwork and acquiring local and global approval will significantly impact customer service and overall product availability in South Africa.			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		8.The benchmark reference Regulatory Authorities that South Africa aligns itself with in terms of registration requirements (section2B(2) of the Act), do not require the importer or distributor information on the label as a single solution, but provide options to ensure local traceability, see examples below. <u>*In the EU*</u> The distributor address does not need to be indicated, unless the distributor performs relabelling/ repacking activities as per Article 16.3 of the EUMDR. In that case this information can be in a			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		document accompanying the device. The importers shall indicate: on the device or on its packaging or in a document accompanying documents their name… etc. *Art 13.3 General obligations of importers* *POINT 3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that*			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		any additional label does not obscure any information on the label provided by the manufacturer. *<u>In AUSTRALIA</u>* *Regulation 10.2 of the Therapeutic Goods (Medical Devices) Regulations implemented on 04 October 2007, requires the name and address of the sponsor of a medical device to be provided in a manner that allows the sponsor to be readily identified by a user of the device.* *Medical device industry justifies compliance with Regulation 10.2 and to which the TGA has accepted this approach, as follows:*			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		The users (surgeons) maintain a business relationship with the product specialists and would therefore have the sponsor's contact details and be able to readily contact if needed. In addition, product specialists are often present during procedures where a surgeon is using our device for the first time and are therefore readily available for questions. *• The name and contact details of the sponsor company can be found in the invoice provided upon purchase of the device.* *• Surgeons would also be able to obtain the sponsor's details via the hospital's procurement system*			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		9. An enforcement of this requirement would incur significant hardship on the business operations of medical device companies to the extent of possibly eliminating the supply of life-saving products to the marketplace. 10. Consideration must be had for the National Environment: Waste Management Act, 2008, as well as the corporate governance obligations on local companies in terms of reporting on its impact on the environment. 11. It is in SAHPRA and the countries interest to support Africa Continental Free Trade Agreement and alignment within the SADC region is key.			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(f)	where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance;		(f) where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance;		
(g)	the ~~lot~~ batch number or serial number, where applicable;	✓	(g) the batch number or serial number, where applicable;		
~~(h)~~	~~the serial number, where applicable;~~				
~~(i)~~(h)	for accessories, the serial number may be substituted with- a control number and for software it may be substituted with a version number;	✓	(h) for accessories, the serial number may be substituted with a control number and for software it may be substituted with a version number;		
~~(j)~~ (i)	the expiry date, where applicable;	✓	(i) the expiry date, where applicable;		
(k)(j)	where there is no indication of the expiry date, the manufacturing date;		(j) there is no indication of the expiry date, the manufacturing date;		
~~(l)~~(k)	an indication of the special storage or handling conditions ~~applicable;~~	✓	(k) an indication of any applicable special storage or handling conditions;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(m)~~(l)	if the medical device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilisation method;	✓	(l) if the medical device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilisation method;		
~~(n)~~(m)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package;	✓	(m) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package;		
~~(o)~~(p)	warnings or precautions, where applicable; and	✓ that needs to be brought to the attention of the user (refer to the EU MDR for wording if necessary)	(p) warnings or precautions, where applicable; and		
~~(p)~~(q)	where appropriate an indication that the medical device is intended for-	✓	(q) where appropriate an indication that the medical device is intended for-		
(i)	single use;	✓	(i) single use;		
(ii)	Clinical trial ~~investigation~~ or	✓ (investigation per ISO 14155:2020)	(ii) clinical trial or premarket clinical		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	premarket clinical performance study;		performance assessment study;		
(iii)	non-clinical research, teaching or testing purposes;	✓	(iii) non-clinical research, teaching or testing purposes;		
(iv)	~~presentation or demonstration purposes;~~ exhibition or appraisal purposes;	✓	(iv) exhibition or appraisal purposes;		
(v)	in vitro diagnostic (IVD) use or Laboratory Developed Tests; and	✓	(v) *in vitro* diagnostic (ND) use or laboratory-developed tests; and		
(vi)	where relevant for professional use only" or "near patient testing" or "point of care" or "self-testing".	-use prescription symbol	(vi) where relevant, "for professional use only" or "near patient testing" or "point of care testing" or "self-testing" or "custom-made".		
(3)	If the medical device ~~is a~~ has been reprocessed ~~medical device~~, the label must ~~state the name of the re-processor and identify the medical device as a reprocessed medical device~~.	✓	(3) If a medical device has been reprocessed, the label must—		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(a)	identify the medical device as having been reprocessed; and	✓	(a) identify the medical device as having been reprocessed; and		
(b)	state the name of the manufacturer responsible for the reprocessing thereof.	✓	(b) state the name of the manufacturer responsible for the reprocessing thereof.		
(4)	If an IVD kit includes individual reagents and articles that may be made available as separate IVDs ~~medical devices~~, ~~they~~ such reagents and articles must comply with the requirements set out in sub-regulation (1)	✓	(4) If an IVD kit includes individual reagents and articles that may be made available as separate IVDs, such reagents and articles must comply with the requirements set out in sub-regulation (1).		
~~**7.**~~	~~**Appeal against decision of Council the Authority**~~	-refer to general comment 5 (s) above	**24. Appeal against the decision of the Authority**		
~~(1)~~	~~A person aggrieved by a decision of the Council may, as contemplated in section 24 of the Act, lodge an appeal against the decision, in writing, within 30 days of being~~		(1) An entity or person who is aggrieved by the decision or lack of decision of the Authority may according to section 24A (1) and (2) of the		This regulations includes elements that are in some respects already included in s24A – the regulations cannot vary the Act and SAMED recommends that it only adds processes

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~notified of the decision of the Council.~~		Act, lodge an appeal to the Chief Executive Officer.		and not restate what is already in s24a.
~~(2)~~	~~Notice of the appeal must be submitted to the Chairperson of the Council, for attention the Registrar, Medicines Control Council, Private Bag X828, Pretoria, 0001~~		(2) Such appeal shall be submitted to the Chief Executive Officer within 30 days of becoming aware of the Authority's decision: -		
			(a) The appellant must submit a letter of appeal regarding the Authority's decision on the company's letterhead (where it is applicable), and the letter should be accompanied by supporting documents/information where possible;		
			(b) The Chief Executive Officer must within 30 days of receipt of the appeal meet and hear the applicant's grievance or complaint, in the absence of legal		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			representatives, to try and resolve the matter;		
			(c) The Chief Executive Officer shall consider the applicant's submission and take a decision;		
			(d) The Chief Executive Officer shall inform the applicant of the outcome of the appeal in writing; and		
			(e) The Chief Executive Officer may uphold or reject an appeal, and in the event the appeal is rejected, the Chief Executive Officer must provide the applicant with written reasons thereof		
~~(3)~~	~~The notice referred to in sub-regulation (2) must set out clearly and succinctly the basis for the appeal.~~				
~~(4)~~	~~The Registrar must within 30 days of receipt of a notice of~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~appeal, in the absence of legal representatives, meet with the appellant to try and resolve the matter.~~				
~~(5)~~	~~If the matter Is not resolved as contemplated in sub-regulation (4). the appellant may, within 30 days of being notified by the Registrar of the failure to resolve the matter, and upon payment of the prescribed fee, request the Minister to convene an appeal committee.~~		(3) Should the Chief Executive Officer and the appellant fail to resolve the matter, Section 24A (3) of the Act, provides that the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee in terms of Section 24A (3) of the Act.		
~~(6)~~	~~The appeal committee -~~		(4) The appeal committee shall: -		
			(a) be appointed within 30 days of receipt of		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			the notice referred to above;		
~~(a)~~	~~must determine the procedure for its hearings;~~		(b) determine the procedure for its hearings; and		
~~(b)~~	~~may, if It considers it necessary, call for oral evidence or argument or summon any person who-~~		(c) if it deems necessary, call for oral evidence or argument or summon any person who:		
~~(i)~~	~~in its opinion may be able to give information concerning the subject of the appeal; or~~		(i) in its opinion may be able to give information concerning the subject of the appeal; or		
~~(ii)~~	~~it believes has in his or her possession or under his or her control a document which has a bearing on the subject of the appeal, to appear before It at a time and place specified in the summons, to be asked questions or to produce a document;~~		(ii) it believes has in his or her possession or under control any document which has a bearing on the subject of the appeal, to appear before it at a time and place specified in the summons, to be asked questions or to produce any such document.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(c)~~	~~must, if it calls for oral evidence or argument-~~		(d) if it calls for oral evidence or argument, -		
~~(i)~~	~~determine the date, time and place for the appeal and must communicate these in writing to the appellant and the Council; and~~		(i) determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Minister; and		
~~(ii)~~	~~administer an oath to, or accept an affirmation from, any person called as a witness at the appeal.~~		(ii) administer an oath to or accept an affirmation from any person called as a witness at the appeal.		
~~(7)~~	~~A person appearing before the appeal committee may be represented by a legal practitioner.~~		(5) Persons appearing before an Appeal Committee may be represented by a legal practitioner.		
~~(8)~~	~~The appeal committee must consider the appeal and make a decision within a period of 30 days from the date on which it first meats to hear the appeal.~~		(6) The Appeal Committee may –		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			(a) set aside or confirm the decision of the Authority;		
			(b) vary the decision of the Authority;		
			(c) direct the Authority to reconsider any matter; or		
			(d) make any finding that is just and equitable in the circumstances.		
~~23.~~ **7.**	**Instructions for use of medical device (EXCLUDING IVD)**	-refer to general comment 5 (l) above	**6. INSTRUCTIONS FOR USE OF A MEDICAL DEVICE WHICH IS NOT AN IVD**		
(1)	Instructions for use shall be available for all devices, in electronic or hardcopy format, except for class A and class B devices where such devices can be used safely without any such instructions. Instructions for the use of a medical device must-		(1) Instructions for the use of a medical device must—		
(a)	appear on or be attached to or packed	-the IFU is not packaged with each	(a) appear on or be attached to or packed	Some products are pack in boxes of 5-10-	See Appendix A. Some

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	with each medical device, **or be available electronically as soft copy**	device but may be downloaded by users - a soft copy is provided -no provision is made for electronic IFUs. Electronic IFU's are appropriate for active, implantable medical devices; implantable devices with their accessories; fixed, installed devices, software etc. The users of these devices are already extensively trained and are capable to refer to the IFU online. Electronic IFUs are always available in the latest revision and more environment friendly. IFUs are not always required or available for class A devices. In EU regulations, Article 7(2) also notes that IFUs are not always	with each medical device,	20 or more and only 1 IFU per box (a) appear on or be attached to or packed with each medical device or provided as Electronic Instructions for Use (eIFU) : 1) (a) appear on or be attached to or packed with each medical device ***or made available electronically***	devices are eligible for eIFU in place of a paper IFU. Globally, manufacturers and regulatory authorities are migrating from hard-copy IFU's to electronic copies of the IFUs. : SAMED recommends that SAHPRA **Adopt electronic instructions for use.** Electronic instructions for use (IFU) can benefit patients, physicians, caregivers, and manufacturers, by increasing the availability, utility, interactivity, and accessibility of IFU. In addition, supplying electronic IFU may have environmental

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		needed for class A devices. We propose that the Regulations Relating to Medical Devices, in line with legislation such as the Electronic Communications and Transactions Act, accept of Electronic Instructions for Use to all professional use instructions for all professional use medical devices regardless of risk class or type. The benefits of such an extension and acceptability are outlined in Appendix A.			benefits, including reduced ethylene oxide emissions, reduced paper usage, and a reduced carbon footprint. It should be noted that in all cases, users would have access to all of the relevant information. Users who do not have access to electronic copy users can request a paper version. The case for electronic IFU is particularly salient when the IFU relates to a software-based product or the software features of a device when the user of the device has access to online information

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					It would be important to allow the possibility to provide IFU in an electronic format. Proposal: the IFU is not packaged with each device but may be downloaded by users - a soft copy is provided It should be pointed out that NO provision is made for electronic IFUs in the regulation, and this should be made transparent. The EU Regulation 2021/2226 allows the provision of instructions for use

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					in electronic form (e-IFU) instead of paper for a selected category of medical devices: -Implants & Active implants and their accessories -Fixed installed devices -Devices with built-in system displaying instructions -Stand-alone software *Only devices and accessories intended for exclusive use **by professional u**sers (use by other*

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					persons is not reasonably foreseeable) are e-IFU eligible in the EU. The users of these devices are already extensively trained and are capable to refer to the IFU online. Electronic IFUs are always available in the latest revision and more environment friendly. We propose an extension of the scope in the Regulations Relating to Medical Devices

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					on the acceptability of Electronic Instructions for Use to all professional use instructions for all professional use medical devices regardless of risk class or type. The benefits of such an extension and acceptability are outlined below. From a harmonisation point of view, a number of SAHPRA aligned RRA's allow for Electronic IFU to be utilized for professional use, such as, but not limited to. Australia, USA, Canada, Saudi Arabia, Turkey, Brazil, Serbia. They stipulate the following:

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					1.The IFU is not packaged with each device but may be downloaded by users - a soft copy is provided 2. No provision is made for electronic IFUs. Electronic IFU's are appropriate for active, implantable medical devices; implantable devices with their accessories; fixed, installed devices, software etc. The users of these devices are already extensively trained and are capable to refer to the IFU online. Electronic IFUs are always available in the latest revision and more environment friendly.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					IFUs are not always required or available for class A devices. Article 7(2) also alerts to IFUs not always needed for class A devices. Benefits to Users for use of electronic IFUs: • Up-to-date information • Increased Availability and Utility • Enhanced accessibility • Reduces the carbon footprint We encourage SAHPRA to support making medical

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					product information available in a way that allows healthcare professionals to better serve patients and patients to practice appropriate and responsible self-care. Extending the e-IFU scope will ensure that we keep up with the pace of innovation seen in other jurisdictions of the world and will ensure that healthcare professionals' benefit from a rapid access to information that is appropriate, up to date, available and accessible.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(b)	be in at least the English language;		(b) in at least the English language;		
(c)	be in type having a minimum legibility; and	-define minimum legibility (recommend font size 6pt)	(c) be in type having a minimum legibility, as determined by the Authority; and		
(d)	contain the particulars specified in sub-regulation (3).		(d) contain the particulars specified in sub-regulation (3).		
(2)	Instructions for the use of a Class A medical device ~~must~~ may be included ~~with the sale of each medical device, however, instructions for the use of Class A medical devices must be included,~~ where applicable.	-Instructions for Use are not needed for Class A and Class B in EU MDR. -in the previous regulations, Class A devices were exempted from being listed on establishment license -refer to general comment 5 (d) above	(2) Instructions for use of a Class A medical device may be included, where applicable as determined by the Authority.	: 2) Instructions for the use of a Class A medical device may be included ***electronically***, where available.	We recommend including the word electronically, as most Class A medical devices have their IFUs available electronically such as for lifestyle apps, fitness devices, etc. Furthermore, not all Class A medical devices require an IFU. In the EU MDR, Class A and B devices do not need an IFU, and in the previous regulations Class A devices were exempted from being listed on the

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					Establishment licences. We request that this be maintained to ensure harmonisation.
~~(1)~~(3)	The instructions for use must contain the following information ~~in at least English;~~		(3) The instructions for use must contain the following information:		
(a)	The name and proprietary name ~~or trade name~~ of the medical device;	-include trade name	(a) the name and proprietary name of the medical device;		
(b)	~~The name and business address of the manufacturer; the registration number of the medical device allocated in terms of section 15(5) of the Act;~~	×-exclude - no localized version of IFUs – creates complexity and cost in supply chain -refer to general comment 5 (l) above	(b) the registration number of the medical device allocated in terms of section 15(5) of the Act;	Delete : ~~b) the registration number of the medical device allocated in terms of section 15(5) of the Act;~~	: Same rationale as for labels
(c)	the-		(c) the---	~~(c) the---~~	
(i)	name and physical address of the holder of the licence as per regulation 13(1)(a)(i) or 13(1) (a)(ii);	×-exclude - no localized version of IFUs – creates complexity and cost in supply chain -refer to general comment 5 (l) above	(i) name and physical address of the holder of the licence as per regulation 12(1)(a)(i) or 12(1) (a)(ii);	~~(i) name and physical address of the holder of the licence as per regulation 12(1)(a)(i) or 12(1) (a)(ii);~~	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(ii)	name and physical address of the original manufacturer; and	✓ legal manufacturer	(ii) name and physical address of the original manufacturer; and	~~(ii) name and physical address of the original manufacturer; and~~	
(iii)	~~name and business address of the holder of the certificate of registration;~~	✗	(iii) name and physical address of the holder of the certificate of registration;	~~(iii) name and physical address of the holder of the certificate of registration;~~	
~~(c)~~(d)	where practical, the approved intended purpose or use of the medical device and where appropriate, the intended user;	✓	(d) where appropriate, the intended user;		
~~(d)~~(e)	residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;	✓	(e) residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;		
~~(e)~~(f)	any specifications that the user may require~~s~~ in order to use the medical device appropriately ~~(e.g. if the device has a measuring function,~~ including but not limited to the degree	✓	(f) any specifications that the user may require in order to use the medical device appropriately, including but not limited to the degree of accuracy claimed in the case of a device		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	of accuracy claimed ~~for it);~~ in the case of a device with a measuring function.		with a measuring function;		
~~(f)~~(g)	if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate;	✓	(g) if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate;		
~~(g)~~(h)	details of any preparatory treatment or handling of the medical device before it is ready for use ~~(e.g. sterilisation, final assembly, calibration, etc.);~~ including but not limited to sterilisation, final assembly or calibration;	✓	(h) details of any preparatory treatment or handling of the medical device required before it is ready for use including but not limited to sterilisation, final assembly or calibration;		
(I)	any requirements for-		(I) any requirements for-		
(i)	special facilities; or	✓	(i) special facilities; or		
(ii)	special training or qualifications of the intended user or other person;	✓	(ii) special training or qualifications of the intended user or other person;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(h)~~	~~any requirements for special facilities, or special training, or particular qualifications of the medical device user or third parties;~~				
~~(i)~~(j)	the information needed to verify whether the medical device is properly installed and is ready to perform ~~safely and~~ as intended by the manufacturer, together with, where relevant -	✓	(j) the information needed to verify whether the medical device is properly installed and is ready to perform as intended by the manufacturer, together with, where relevant-		
(i)	details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;	✓	(i) of the nature, and frequency of preventive and regular maintenance, and of any preparatory cleaning or disinfection;		
(ii)	identification of any consumable components and now to replace them;	✓	(ii) identification of any consumable components and how to replace them;		
(iii)	information on any necessary calibration to ensure that the	✓	(iii) information on any necessary calibration to ensure that the		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	medical device operates property and safely during its intended life span; and		medical device operates properly and safely during its intended life span; and		
(iv)	methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing-medical devices;	✓ - add "where appropriate" in each clause	(iv) methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices		
~~(j)~~(k)	an indication of any special transport, storage or handling ~~condition that applies;~~ requirements		(k) an indication of any special transport, storage or handling requirements;		
~~(k)~~(l)	if the medical device is supplied sterile, instructions in the event of the sterile packaging being damaged before use;	-consider if this is necessary -is this currently being done for unsterile kits?	(l) if the medical device is supplied sterile, instructions in the event of the sterile packaging being damaged before use;		
~~(l)~~(m)	if the medical device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterllisation;		(m) if the medical device is supplied non-sterile with the intention that is sterilised before use, the appropriated instruction for sterilisation;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(m)~~(n)	if the medical device is reusable, information -		(n) if the medical device is reusable, information-		
(i)	on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilisation and;	-consider if this is necessary -is this currently being done for unsterile kits?	(i) on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilisation; and		
(ii)	~~including information to identify when the medical device should no longer be reused (e.g. signs of material degradation or the maximum number of allowable reuses);~~including signs of material degradation or the maximum number of allowable reuses;		(ii) to identify when the medical device should no longer be reused including signs of material degradation or the maximum number of allowable reuses;		
~~(n)~~(o)	for medical devices intended for use together with other medical devices or general purpose equipment-		(o) if a medical device is intended for use together with other medical devices or general-purpose equipment-		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(i)	information to identify such medical devices or equipment in order to obtain a safe combination; and		(i) information to identify such medical devices or equipment, in order to obtain a safe combination; and		
(ii)	information on any known restrictions to combinations of medical devices-and equipment;		(ii) information on any known restrictions to combinations of medical devices and equipment		
~~(o)~~(p)	if the medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes-		(p) if the medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes-		
(i)	detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and		(i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and		
(ii)	the means of protecting the patient user, or ~~third party~~ other person from unintended radiation		(ii) the means of protecting the patient, user, or other person from unintended radiation during use of the medical device;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	during use of the medical device;				
~~(p)~~(q)	information that allows the user and patient to be informed of warnings, precautions, measures to be taken and limitations of use regarding the medical device which information must cover, where appropriate-		(q) information that allows the user and patient to be informed of warnings, precautions, measures to be taken and limitations of use regarding the medical device which information must cover, where appropriate		
(i)	warnings, precautions and measures to be taken in the event of malfunction of the medical device or changes in its performance that may affect safety;		(i) warnings, precautions and measures to be taken in the event of malfunction of the medical device or changes in its performance that may affect safety;		
(ii)	warnings, precautions and measures to be taken in regard to the exposure to reasonably foreseeable external influences or environmental		(ii) warnings, precautions and measures to be taken in regard to the exposure to reasonably foreseeable external influences or		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;		environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;		
(iii)	warnings, precautions and measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the medical device		(iii) warnings, precautions and measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g., electromagnetic interference emitted by the medical device		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	affecting other equipment);		affecting other equipment);		
(iv)	if the medical device administers a scheduled substance or a biological substance, any limitations or incompatibility in the choice of substance to be delivered;	updated terminology	(iv) if the medical device administers a scheduled substance or a biological substance, any limitations or incompatibility in the choice of substance to be delivered;		
(v)	warnings, precautions and limitations related to the scheduled substance or biological substance that is incorporated into the medical device as an integral part of the medical device; and	updated terminology	(v) warnings, precautions and limitations related to any scheduled substance or biological substance that is incorporated into the medical device as an integral part of the medical device; and		
(vi)	precautions related to materials incorporated into the medical device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic		(vi) precautions related to materials incorporated into the medical device that are potentially carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	reaction· of the patient or user or any other person;		reaction of the patient, user or any other person;		
~~(q)~~(r)	warnings and precautions to be taken related to the disposal of the medical device, its accessories and the consumables used with it if any. ~~This information must cover,~~ provided that this information includes, where appropriate -		(r) warnings and precautions to be taken related to the disposal of the medical device, its accessories and the consumables used with it, if any: provided that this information includes, where appropriate—		
(i)	infection or microbial hazards ~~(e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);~~ associated with a medical device which may include an implant which has been removed;		(i) infection or microbial hazards associated with a medical device which may include an implant which has been removed		
(ii)	environmental hazards ~~(e.g.~~ such as batteries or materials that emit		(ii) environmental hazards such as batteries or materials		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	potentially hazardous levels of radiation~~);~~ and		that emit potentially hazardous levels of radiation; and		
(iii)	physical hazards ~~(e.g. from sharps);~~		(iii) physical hazards;		
~~(r)~~(s)	for medical devices intended for use by a ~~lay person~~ person who is not a health care provider, the circumstances when the user must consult with a healthcare ~~professional~~ provider;		(s) for medical devices intended for use by a person who is not a health care provider, the circumstances when the user must consult with a health care provider or veterinarian;		
~~(s)~~(t)	the date of issue or latest revision of the instructions for use and, ~~where appropriate, an identification number; and~~		(t) the date of issue or latest revision of the instructions for use; and		
~~(t)~~(u)	appropriate service and maintenance instructions for the medical device and associated technical equipment and ~~medical devices,~~ where applicable.		(u) appropriate service and maintenance instructions for the medical device and associated technical equipment, where applicable.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~24~~.8.	**Instruction for use of IVD**	-refer to general comment 5 (l) above	**7. Instructions for use of IVD**		
(1)	The instructions for the use of an IVD device must - ~~contain the following in at least English:~~		(1) Instructions for the use of an IVD must—		
(a)	appear on or be attached to or packed with each IVD, **or be available electronically as soft copy**	-the IFU is not packaged with each IVD but may be downloaded by users - a soft copy is provided	(a) appear on or be attached to or packed with each IVD;	(a) appear on or be attached to or packed with each IVD or provided as Electronic Instructions for Use (eIFU)	Some IVDs are eligible for eIFU in place of a paper IFU. Globally, manufacturers and regulatory authorities are migrating from hard-copy IFU's to electronic copies of the IFUs.
(b)	be in at least the English language;		(b) be in at least the English language;		
(c)	be in type having a minimum legibility; and	-define minimum legibility	(c) be in type having a minimum legibility, as determined by the Authority; and		
(d)	contain the particulars specified in sub-regulation (3).		(d) contain the particulars specified in sub-regulation (3).		
(2)	Instructions for the use of a Class A IVD may be included where applicable.	-refer to general comment 5 (d) above			

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(3)	The instructions for use must contain the following:		(2) The instructions for use must contain the following:		
(a)	The name ~~or trade name;~~ and proprietary name of the IVD;	-include trade name	(a) The name and proprietary name of the IVD;		
(b)	~~the registration number of the medical device allocated in terms of section 15(5) of the Act;~~	-exclude-no localised version of IFUs – creates complexity and cost in supply chain	(b) the registration number of the medical device allocated in terms of section 15(5) of the Act;	Delete	
(b)(c)	the-		(c) the-		
(i)	~~name and address of the~~ ~~manufacturer; holder of the certificate of registration;~~	-exclude -no localised version of IFUs – creates complexity and cost in supply chain	(i) name and physical address of the holder of the certificate of registration;	Delete	
(ii)	name and business address of the licensee as per regulation 13(1)(a)(i) or 13(1)(a)(ii); and	localised	(ii) name and physical address of the licensee as per regulation 12(1)(a)(i) or 12(1)(a)(11); and	Delete	
(iii)	name and physical address of the original manufacturer;	✓ legal	(iii) name and physical address of the original manufacturer;		
~~(c)~~(d)	the intended purpose and use, including but not limited to-		(d) the intended purpose, including but not limited to-		
(i)	what is detected;		(i) is detected;		

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(ii)	~~its function;~~ the function of the IVD.		(ii) the function of the 1VD;		
(iii)	the specific disorder, condition or risk factor of interest that ft is intended to detect, define or differentiate;		(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;		
(iv)	whether it is automated or not;		(iv) whether it is automated or not;		
(v)	whether it is qualitative or quantitative;		(v) whether it is qualitative or quantitative;		
(vi)	the type of specimens required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and		(vi) the type of specimens required (e.g., serum, plasma, whole blood, tissue biopsy, urine); and		
(vii)	testing population;		(vii) testing population;		
~~(d)~~(e)	an indication that it is for *in vitro* diagnostic use and, where relevant, for "professional use only" for "near patient testing", for "point of care", for "self-testing" or for "research use only";		(e) an indication that it is for in vitro diagnostic use and, where relevant, for "professional use only", for "near patient testing", for "point of care", for "self-testing" or for "research		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(e)~~(f)	the intended user, as appropriate;		(f) the intended user, as appropriate;		
~~(f)~~(g)	the test principle;		(g) the test principle;		
~~(g)~~(h)	whether provided as an individual reagent or in an IVD kit with other appropriate articles, a description of -		(h) whether provided as an individual reagent or in a group with other appropriate articles, a description of-		
(i)	the reagent, calibrators and controls and appropriate articles;		(i) the reagent, calibrators, controls and appropriate articles;		
(ii)	any limitation upon their use of the IVD kit, such as ~~(e.g. suitable~~ suitability for a dedicated instrument ~~only);~~		(ii) any limitation upon the use of the reagent or the IVD kit, such as suitability for a dedicated instrument;		
(iii)	the composition of the reagent by nature and concentration of the active ingredients; and		(iii) the composition of the reagent by nature and concentration of the active ingredients; and		
~~(h)~~(iv)	~~the composition of the reagent product by nature and concentration of the active~~		(iv) A statement, where appropriate, that the medical device contains other ingredients which		

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	~~ingredients of the reagents or kit as well as~~ a statement, where appropriate, that the medical device contains other ingredients which might influence the measurement;		might influence the measurement;		
(i)	a list of materials provided and a list of special materials required but not provided;		(i) a list of materials provided and a list of special materials required but not provided;		
(j)	~~for IVDs~~ if intended for use together with other IVDs ~~or~~ , medical devices, or general purpose equipment-		(j) if intended for use together with other IVDs, medical devices, or general-purpose equipment-		
(i)	information to identify such IVDs, medical devices or equipment in order to obtain a safe combination; and		(i) information to identify such IVDs, medical devices or equipment, in order to obtain a safe combination; and		
(ii)	information on any known restrictions to combinations of ~~medical devices~~ IVDs and equipment;		(ii) information on any known restrictions to combinations of IVDs, medical devices and equipment;		

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(k)	an indication of any special transport , storage and handling requirements ~~conditions that apply;~~		(k) an indication of any special transport, storage and handling requirements;		
(l)	in use stability which may include, the storage conditions, and shelf life following the first opening of the ~~primary~~ immediate container or primary packaging, together with the storage conditions and stability of working solutions, where this is relevant;		(l) in use stability which may include the storage conditions, and shelf life following the first opening of the immediate container or primary packaging, together with the storage conditions and stability of working solutions, where relevant;		
(m)	if the IVD is supplied as sterile, instructions in the event of the sterile packaging being damaged before use;		(m) if the IVD is supplied sterile, instructions in the event of the sterile packaging being damaged before use;		
(n)	information that allows the user to be informed of warnings, precautions, measures to be taken and limitations of use regarding the IVD,		(n) information that allows the user to be informed of warnings, precautions, measures to be taken and limitations of use regarding the IVD,		

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	which information must cover, where appropriate-		which information must cover, where appropriate-		
(i)	warnings, precautions and measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance;		(i) warnings, precautions and measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance;		
(ii)	warnings, precautions and measures to be taken with regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects , electrostatic discharge, radiation associated		(ii) warnings, precautions and measures to be taken with regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	with diagnostic or therapeutic procedures, pressure, humidity, or temperature;		procedures, pressure, humidity, or temperature;		
(iii)	warnings, precautions and measures to be taken with regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by the medical device affecting other equipment, where applicable; and		(iii) warnings, precautions and measures to be taken with regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by such medical device affecting other equipment, where applicable; and		
(iv)	precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or		(iv) precautions related to materials incorporated into the IVD that are		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	could result in sensitization or allergic reaction;		carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction;		
(o)	warnings and precautions related to potentially infectious material that is included in the IVD;		(o) warnings and precautions related to potentially infectious material that is included in the IVD;		
(p)	Where relevant, requirements for special facilities including clean room environment, radiation safety or particular qualifications of the medical device user;		(p) where relevant, requirements for special facilities including clean room environment, radiation safety or particular qualifications of the medical device user;		
(q)	conditions for collection, handling, and preparation of the specimens;	-correction	(q) conditions for collection, handling, and preparation of the specimen;		
(r)	details of any preparatory treatment or handling of the IVD before ~~f~~it is ready for use including reconstitution and calibration where applicable;	-correction	(r) details of any preparatory treatment or handling of the 1VD before it is ready for use including reconstitution and calibration where applicable;		

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(s)	the information needed to verify whether the IVD is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant-		(s) the information needed to verify whether the IVD is properly installed and is ready to perform as intended by the manufacturer, together with, where relevant-		
(i)	details of the nature, and frequency, of preventative and regular maintenance including cleaning and disinfection;		(i) details of the nature, and frequency, of preventive and regular maintenance including cleaning and disinfection;		
(ii)	identification of any consumable components and how to replace them;		(ii) identification of any consumable components and how to replace them		
(iii)	information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span; and		(iii) information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span; and		
(iv)	methods of mitigating the risks encountered by persons involved in		(iv) methods of mitigating the risks encountered by persons involved in		

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	installing, calibrating or servicing an IVD;		installing, calibrating or servicing an 1VD;		
(t)	where relevant, recommendations for quality control procedures;		(t) where relevant, recommendations for quality control procedures;		
(u)	the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and reference measurement procedures of higher order;		(u) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and reference measurement procedures of higher order;		
(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing must be considered;		(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing must be considered;		
(w)	analytical performance characteristics, such as sensitivity, specificity, and accuracy		(w) analytical performance characteristics, as determined by the Authority such as		

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			sensitivity, specificity, and accuracy		
(x)	where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;		(x) where relevant, clinical performance characteristics, as determined by the Authority such as diagnostic sensitivity and diagnostic specificity;		
(y)	where relevant reference intervals;		(y) where relevant, reference intervals;		
(z)	information on interfering substances or limitations such as visual evidence of hyperlipidaemia or hemolysis, age of specimen that may affect the performance of the assay;		(z) information on interfering substances or limitations such as visual evidence of hyperlipidaemia or haemolysis, age of specimen that may affect the performance of the assay;		
(aa)	warnings or precautions to be taken related to the disposal of the medical device, its accessories, and the consumables used with it, if any, which information		(aa) warnings or precautions to be taken related to the disposal of the IVD, its accessories, and the consumables used with it, if any, which information must		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	must cover, where appropriate-		cover, where appropriate-		
(i)	infection or microbial hazards;		(i) infection or microbial hazards;		
(ii)	environmental hazards; and		(ii) environmental hazards; and		
(iii)	physical hazards;		(iii) physical hazards;		
(bb)	for an IVD intended for use by a ~~lay person~~ person who is not a health care provider, the circumstances when the user must consult with a healthcare professional;		(bb) for an IVD intended for use by a person who is not a health care provider, the circumstances when the user must consult with a health care provider or veterinarian;		
(cc)	where relevant, a bibliography;		(cc) where relevant, a bibliography;		
(dd)	the date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and		(dd) the date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and		
(ee)	appropriate maintenance instructions for technical IVD		(ee) appropriate maintenance instructions for technical IVD		

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	machines, where applicable.		machines, where applicable.		
~~(8)~~ 9.	**Application for registration of a medical device ~~or IVD~~**	Please note that no devices have been registered, there has been no call-up and no s36 exemption from call-up. Some "registrations" have just been unlawfully added as "conditions" on licenses, and some have received s21 "authorisations" without having applied for s21's. This practice must stop.	**8. APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE**		
~~(8)~~ (1)	An application for registration of a medical device must be made in respect of each individual medical device ~~or IVD, or medical device or IVD group or family~~ or modification thereof, ~~as determined by the Council.~~ impacting the safety, effectiveness, classification risk, or	-Where applicable, submissions shall be made per product family/ group, and not necessarily for each individual medical device as indicated	(1) An application for the registration of each type of medical device, family or group or modification thereof as determined by the Authority and published as a notice in the Government Gazette, must be made providing details of the class and type of	(1) An application for the registration of each type of medical device or IVD, family or group or system modification thereof as determined by the Authority and published as a notice in the Government Gazette, must be made providing details of the class and type of	Addition of system as an additional grouping criteria.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	changes the intended use		medical device, family or group as the case may be.	medical device or IVD, family or group or system as the case may be.	
(2)	A manufacturer or distributor residing in the Republic may submit an application for the registration of a medical device on an application form (electronic form process) obtainable from the Authority	Reference South African legislation NEMA: Waste - include the proposal to introduce the opportunity given by green submissions (using electronic applications) to improve efficiency, data integrity and security and sustainability. Green submissions will contribute to a significant simplification of the regulatory submissions and some tangible environmental benefits by eliminating paper and travel for physical submission.	(2) A manufacturer or distributor residing in the Republic must submit an application for the registration of a medical device on an application form obtainable from the Authority. : A manufacturer or distributor residing in the Republic may submit an application for the registration of a medical device on an ***online/electronic*** application form obtainable from the Authority.	A manufacturer or distributor residing in the Republic must submit an application for the registration of a medical device or IVD on an application form obtainable from the Authority. ; Green submissions will contribute to a significant simplification of the regulatory submissions and some tangible environmental benefits by eliminating paper and travel for physical submission. It has been noted that the registration process will be done via an online/electronic system. We recommend including	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		Efficiency and Environmental Benefits: The Global Environmental Emergency arises more than ever the need of more sustainable processes to contribute in a holistic way to the safeguard of our Environment. Digital solutions represent an extraordinary opportunity to contribute to the sustainability of our Environment without compromising but indeed increasing, the effectiveness of our processes. We noticed and appreciate that some countries to reduce the backlog of regulatory submissions related to the Pandemic, are in the process of		this into the regulation for transparency.	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		reviewing, or have already provided, opportunities for continued registration of devices during the COVID-19 emergency; some best-practice examples include: -Use of electronic submissions to replace physical delivery of documents -Acceptance of electronic and soft copies of documents, instead of the usual wet signed paper versions, where e-signature is an alternative to an ink signature and stamp -On-line submissions activated through specific, protected web portals e.g. use of google drive or			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		SharePoint-one drive, hosted by the HAs. Some Authorities implemented new digital databases like in Serbia, Montenegro, Poland, Turkey and just recently Egypt while other countries in EU, US and Asia-Pacific have limited the impact of the Pandemic having already adopted these solutions years back Accepting documentations signed by the official local representative of the manufacturer			
~~(2)~~(3)	~~An~~ The application referred to sub-regulation (1) ~~for the registration of a medical device or IVD~~ must include the particulars of the		(3) The application referred to sub-regulation (1) must, include the particulars of the authorised representative in South Africa who must be		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	authorized representative in South Africa who ~~is~~ must be responsible for communication with the ~~Council~~ Authority.		responsible for communication with the Authority.		
~~(3)~~(4)	~~An~~ application contemplated in sub-regulation (1) ~~for the registration of a medical device or IVD must be made on the appropriate form obtainable from the Registrar and~~ must be accompanied by -		(4) The application contemplated in sub-regulation (1) must be accompanied by—		
(a)	~~the completed application form;~~ the appropriate form which is obtainable from the Authority which has been completed by the applicant;	-product registration requirements not finalized by SAHPRA – form pending and so is the official call-up notice required by section 14(2) in the Act.	(a) the appropriate form which is obtainable from the Authority which has been completed by the applicant;		
(b)	a proposed label for ~~use on~~ the medical device ~~or IVD~~, if applicable;		(b) a proposed label for use on the medical device, if applicable;	(b) a proposed label for use of the medical device or IVD, if applicable;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(c)	the instructions for use of the medical device ~~or IVD;~~		(c) the instructions for use of the medical device;	(c) the instructions for use of the medical device or IVD;	
(d)	a copy of the licence referred to in regulation13(1)(a)(i) or 13(1)(a)(ii);		(d) a copy of the licence referred to in regulationl2(1)(a)(i) or 12(1)(a)(ii);		
~~(d)~~(e)	~~where applicable,~~ a certified copy of the-		(e) a certified copy of the	(e) where relevant, a certified copy of the-	
~~(i)~~	~~a copy of the manufacturer licence or distributor licence together with a conformity assessment certificate of a Quality Management System for the local medical device establishment as determined by the Council; and~~				
~~(ii)~~(i)	~~a certified copy of the conformity assessment~~ certificate(s) ~~to a quality standard, as determined by the Council, for the medical device or IVD to be registered, and which is~~ issued by a	-consider that certification by local CABs are not yet in place -refer to general comment 5 (q) above	(i) certificate(s) issued by a conformity assessment body;	(i) certificate(s) issued by a conformity assessment body; where applicable to classification and quality standard or;	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	Conformity Assessment Body;				
(ii)	test result(s); or		(ii) test result(s); or		
(iii)	inspection certification, for the medical device		(iii) inspection certification,	Remove inspection and reference to Authority (iii) safety or performance certification,	
	for which the application is being made, issued by a conformity assessment body;		for the medical device for which the application is made, as determined by the Authority	of the medical device or IVD for which the application is made.	A design examination certificate issued by a notified body is usually issued for medical devices or IVDs that are Class C or D. This information could be included as part of the technical file.
~~(e)~~(f)	any other information as ~~the Council~~ may be required by the Authority ~~determine~~; and		(f) any other information as may be required by the Authority; and		
~~(f)~~(g)	the applicable application fee.	-no fee guideline for MDs released, currently using fees published for medicines	(g) the applicable application fee.		
~~(4)~~(5)	The information referred to in sub-		(5) The information referred to in sub-		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	regulation ~~(3)~~(4) must ~~at least~~ be submitted in English.		regulation (4) must be submitted in English.		
~~(5)~~(6)	The application form referred to in sub-regulation ~~(3)(a)~~ (1) must contain at least the following inflammation:		(6) The application form referred to in sub-regulation (1) must contain at least the following information:		
(a)	Particulars of the prospective holder of the certificate of registration:		(a) Particulars of the prospective holder of the certificate of registration, including:		
(i)	Name;		(i) name;		
(ii)	Business Address;		(ii) physical address;		
(iii)	Postal Address;		(iii) postal address;		
(iv)	Telephone Number;		(iv) telephone number;		
(v)	Fax Number, where available;		(v) fax number, if applicable;		
(vi)	e-mail address, if applicable ; and		(vi) e-mail address, if applicable; and		
(vii)	contact details of the authorised representative referred to in sub-regulation ~~(2)~~ (3) and;		(vii) contact details of the authorised representative referred to in sub-regulation (3); and		
(b)	Particulars of the medical device , including- ~~or IVD:~~		(b) particulars of the medical device, including-	(b) particulars of the medical device or IVD, including-	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(i)	~~The~~ proposed proprietary name and group or family name, make and model, where applicable;		(i) proposed proprietary name and group or family name, and make and model, where applicable;		
(ii)	intended purpose ~~or use;~~		(ii) intended purpose;		
(iii)	Classification as per regulation 5; ~~and registration status in recognized authorities outside the Republic, as determined by the Council, and proposed classification in the Republic;~~		(iii) classification as per regulation 4;		
(iv)	classification and registration status with other regulatory authorities recognised by the Authority;		(iv) classification and registration status with other regulatory authorities recognised by the Authority;		
~~(iv)~~(v)	nomenclature system code;		(v) nomenclature system code;		
~~(v)~~(vi)	in the case of a medical device which contains a medicine or scheduled substance, the approved name		(vi) in the case of a medical device which contains a medical or scheduled substance, the approved name		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	and quantity of each active ingredient or biological substance; and~~combination device, the name and quantity of the scheduled substances or biological substances;~~		and quantity of each active ingredient or biological substance; and		
~~(vi)~~(vii)	the name and physical address of the original manufacturer.~~; and~~		(vii) the name and physical address of the original manufacturer.		
~~(vii)~~	~~the name and physical address of the clinical investigation sites, where applicable.~~				
(7)	Where a medical device is registered with a regulatory body outside the Republic, the following information in respect of the medical device must also accompany the application:		(7) Where a medical device is registered with a regulatory body outside the Republic, the following information in respect of the medical device must also accompany the application:	(7) Where a medical device or IVD is registered with a regulatory body outside the Republic, the following information in respect of the medical device or IVD must also accompany the application:	
(a)	A certified copy (electronic or hard	-employ current best practice	(a) A certified copy of the certificate of		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	copy) of the certificate of registration, market authorisation or premarket approval, where applicable;		registration, market authorisation or premarket approval, where applicable;		
(b)	instructions for use, where applicable;		(b) instructions for use, where applicable;		
(c)	conditions of registration, where applicable; and		(c) conditions of registration, where applicable; and		
(d)	any other information as may be required by the Authority.		(d) any other information as may be required by the Authority.		
~~(6)~~(8)	A medical device ~~or IVD,~~ in respect of which an application for registration is made, must comply with the Essential Principles ~~for Safety and Performance of Medica Devices which include requirements for quality, safety and performance, as determined by the Council.~~		(8) A medical device, in respect of which an application for registration is made, must comply with the essential principles.	A medical device or IVD, in respect of which an application for registration is made, must comply with the essential principles.	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(7)~~(9)	An application for registration of a medical device ~~or IVD~~ must be accompanied by a declaration of conformity ~~by the authorized representative as determined by the Council,~~	-confirmation required that the DOC from Legal Manufacturer is acceptable (in terms of international regulatory authorities recognized by SAHPRA)	(9) A declaration of conformity to the essential principles, signed by the Authorised Representative must accompany an application for registration of a medical device as determined by the Authority.	(9) A declaration of conformity to the essential principles, signed by the Authorised Representative of the legal manufacturer must accompany an application for registration of a medical device or IVD .	
~~(9)~~	~~In an instance where a medical device or IVD in respect of which an application is made, is registered with a regulatory body outside the Republic, the following information in respect of the medical device or IVD must accompany the application:~~				[Add provision on exclusion of class A and [B ?] devices from registration, e.g.: Class A and B medical devices and IVDs must be listed at the Authority according to a schedule for such listing published by the Authority and containing the following details … [insert what should be on listing.]
~~(a)~~	~~A certified copy of the certificate of registration or~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~premarket approval, where applicable;~~				
~~(b)~~	~~instructions for use, where applicable;~~				
~~(c)~~	~~conditions of registration; and~~				
~~(d)~~	~~any other information determined by the Council.~~				
~~9.~~ 10.	**Information that must appear in register for medical devices ~~or IVDs~~**		**9. INFORMATION THAT MUST APPEAR IN REGISTER FOR MEDICAL DEVICES**		
	The medical device ~~or IVD~~ register must, in respect of a registered medical device ~~or IVD,~~ contain the following information:		The medical device register must, in respect of any registered medical device, contain the following information:	The medical device and IVD register must, in respect of any registered medical device or IVD, contain the following information:	
(a)	The -		(a) the-		
(i)	Name, ~~and~~ group or family name and;		(i) name, group or family name; and	(i) name, group or family or system name; and	
(ii)	~~and the~~ ~~make and model, where applicable, of the medical device or IVD;~~	-listing the make and model of every device in a family may be onerous. New models, outside the scope of	(ii) make and model, where applicable;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		the devices registered, could be covered by regulations governing modifications			
(b)	the registration number allocated to the medical device ~~or IVD;~~		(b) the registration number allocated to the medical device;	(b) the registration number allocated to the medical device or IVD;	
(c)	in the case of a ~~combination device, the name and quantity of the scheduled substances or biological substances in the medical device;~~ medical device which contains a medicine or scheduled substance, the name and quantity of each medicine or scheduled substance;		(c) in the case of a medical device which contains a scheduled substance, the name and quantity of each scheduled substance;		
(d)	~~the intended purpose or use of the medical device or IVD;~~ the name of the holder of the certificate of registration and the authorized representative;		(d) the name of the holder of the certificate of registration;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(e)	the name of the ~~holder of the certificate of registration;~~ licence holder referred to in regulation13(1)(a)(i) or 13(1)(a)(H);		(e) the name of the licence holder referred to in regulation12(1)(a)(i) or 12(1)(a)(ii);		
(f)	the name and address of the		(f) the name and physical address of the-	: ~~10. (f) the name and address of the- (i) original manufacturer(s); and (ii) manufacturing facilities;~~	Learning from medicines and the backlog created due to administrative changes, we recommend deletion of this requirement as this would mean that every time a manufacture amends address or name, it will require variation and amendment of register. Rather manage this via a variation guideline and using an online tool to ensure ease of notification and implementation.
(i)	original manufacturer(s); and		(i) original manufacturer(s); and	(i) legal manufacturer(s); and	Manufacturers could have both legal manufacturers and physical manufacturers

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					contracted to the legal manufacturers.
(ii)	manufacturing facilities;		(ii) manufacturing facilities;	(ii) physical manufacturing facilities;	Manufacturers could have both legal manufacturers and physical manufacturers contracted to the legal manufacturers.
(g)	the date of registration of the medical device ~~or IVD;~~		(g) the date of registration of the medical device;	(g) the date of registration of the medical device or IVD;	
(h)	the conditions of registration of the medical device ~~or IVD;~~		(h) the conditions of registration of the medical device;	(h) the conditions of registration of the medical device or IVD;	
(i)	the class of medical device ~~or IVD;~~ and		(i) the class of medical device; and	(i) the class of medical device or IVD; and	
(j)	the nomenclature system code allocated to the medical device ~~or IVD.~~		(j) the nomenclature system code allocated to the medical device.	(j) the nomenclature system code allocated to the medical device or IVD.	
~~10.~~ 11.	~~Amendment to medical device and IVD Register~~ APPLICATION FOR AMENDMENT TO REGISTER FOR MEDICAL DEVICES		**10. APPLICATION FOR AMENDMENT TO REGISTER FOR MEDICAL DEVICES**		
~~(1)~~	~~A holder of a certificate of registration may submit to the Registrar~~		(1) An application for an amendment of an		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~an application on a form, as determined by the Council, to amend an entry made In the medical devices or IVDs register with regard to a particular medical device or IVD.~~		entry in the register for medical devices in terms of section 15A of the Act must be accompanied by the relevant fee and must contain the following particulars:		
~~(2)~~ (1)	~~The~~ An application for an amendment of entry in the register for medical devices in terms of section 15A of the Act ~~referred to in sub-regulation (1)~~ must be accompanied by the relevant ~~prescribed~~ fee, and must contain the following particulars ~~information:~~	-fee requirements need to be advised by SAHPRA for MDs			
(a)	The registration number of the medical device ~~or IVD;~~		(a) the registration number of the medical device;		
(b)	the name of ~~and~~ the holder of the certificate of registration and the		(b) the name of the holder of the certificate of registration and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	authorised representative;		the authorised representative;		
(c)	business address of the holder of the holder of the certificate of registration;		(c) physical address of the holder of the certificate of registration;		
~~(c)~~(d)	~~a~~ declaration by the ~~authorized representative~~ by the holder of the certificate of registration that the information furnished is complete and accurate;		(d) declaration by the holder of the certificate of registration that the information furnished is complete and accurate;		
~~(d)~~(e)	the details of the amendment applied for;		(e) the details of the amendment applied for; and		
~~(e)~~	~~the manufacturer licence number of the manufacturer or the distributor licence number of the distributor; and~~				
(f)	any other information that may be required by the Authority		(f) any other information as may be required by the Authority.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~determined by the Council.~~				
(2)	Where a new certificate is issued in terms of section 15A(3) of the Act-		(2) Where the provisions of section 11(1) are approved, an amended certificate will be issued in terms of section 16A (3) of the Act.		
(a)	~~the original certificate of registration must be returned to the Authority; or~~	-if SAHPRA retains ownership of the registration, it cannot be expected for the companies to pay a certificate fee. -registration information should be kept current on the website, thereby allowing any person to verify a company's licensing and/or registration status.			
(b)	~~if the original certificate of registration is lost, an affidavit must be submitted to the Authority confirming~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~that the certificate of registration is lost.~~				
~~**12.**~~	~~**Registration Certificate**~~				
	~~The Registrar must, after a medical device or IVD has been registered, issue a registration certificate substantially in the form shown below:~~				
	~~**MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT NO.101 OF 1965)**~~				
	~~**MEDICAL DEVICE OR IVD REGISTRATION CERTIFICATE**~~				
	~~It is. hereby certified that registration of the medical device or IVD described below has been approved by the Council subject to the conditions indicated.~~				
~~1.~~	~~Name~~				
~~2.~~	~~Registration number~~				
~~3.~~	~~Class of medical device or IVD~~				
~~4.~~	~~In the ease of combination medical~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~devices the name and quantity of the scheduled substance(s), or biological substance(s)~~				
~~5.~~	~~Nomenclature system or code~~				
~~6.~~	~~Conditions under which the medical device or IVD is registered~~				
~~7.~~	~~Registered in the name of (holder of certificate of registration)~~				
~~8.~~	~~Name and physical address of the original manufacturer~~				
~~9.~~	~~Date of registration~~				
	~~Registrar~~				
	~~Issued at_____on_____ 20___~~				
12.	**CERTIFICATE OF REGISTRATION**		**11. CERTIFICATE OF REGISTRATION**		
	A certificate of registration for a medical device as contemplated in section 15(3) of the Act must be in a form	Remove from Annexure 1 "original manufacturer" – this is a subcontracted process covered under ISO13485 certification	A certificate of registration for a medical device as contemplated in section 15(3) of the Act shall be in a form		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	substantially similar to the form contained in Annexure 1.	– for sterile products, sterilisation is the end process. However, the release to market could also be viewed as the final manufacturing step. The concept of "original manufacturer" is ambiguous and misleading to the public. The legal entity that places the product on the market is the "manufacturer".	substantially similar to the form contained in Annexure 1.		
~~**13.**~~	~~**Parts and components**~~				
~~(1)~~	~~A person who sells an article intended specifically to replace an identical or similar integral part or component of a medical device or IVD, that is defective or worn, in order to maintain or re-establish the function of the medical device or IVD without significantly changing~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~its performance or safety characteristics, must-~~				
~~(a)~~	~~ensure that the article does not adversely affect the safety and performance of the medical device or IVD; and~~				
~~(b)~~	~~Keep substantiating evidence and on request make the evidence available to the Council.~~				
~~(2)~~	~~An article that is Intended specifically to replace a part or component of a medical device or IVD and that significantly changes the performance or safety characteristics of the medical device or IVD is considered to be a medical device or IVD.~~				
13.	**LICENCE TO MANUFACTURE, DISTRIBUTE OR**		**12. LICENCE TO MANUFACTURE, DISTRIBUTE OR**		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	WHOLESALE MEDICAL DEVICES		**WHOLESALE MEDICAL DEVICES**		
(1)	~~A manufacturer, wholesaler or distributor~~ An application for a licence referred to in section 22C(1)(b) of the Act must-		(1) An application for a licence referred to in section 22C(1)(b) of the Act, must—		
(a)	~~prior to commencing business-~~ be made on an electronic format provided by~~form obtainable from~~ the Authority for a licence-	-implement appropriate technology at SAHPRA	(a) be made on a form obtainable from the Authority for a licence-		
(i)	~~apply to the Council for-~~ to manufacture a medical device, which may include the manufacture, import, distribution or export of a medical device;		(i) to act as a manufacturer;	(i) to act as a manufacturer; to manufacture a medical device or IVD, which may include the manufacture, import, distribution or export of a medical device or IVD;	in line with scope of activities on licence for manufacturer.
(ii)	to distribute a medical device, which may include the distribution, import or export of a medical device; or		(ii) to act as a distributor; and	(ii) to act as a distributor; to distribute a medical device or IVD, which may include the distribution, import or	in line with scope of activities on licence for distributor.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
				export of a medical device or IVD; or	
~~(iii)~~	~~to wholesale a medical device;~~	-refer to general comment 5 (b) above	(iii) to act as a wholesaler.		
~~(aa)~~	~~a manufacturer licence to manufacture, import or export medical devices or IVDs; or~~				
~~(bb)~~	~~a distributor licence to import, export and distribute medical devices or IVDs; or~~				
~~(cc)~~	~~a wholesale licence to act as wholesaler of medical devices or IVDs;~~				
~~(ii)~~	~~appoint and designate an authorised representative who must reside in South Africa~~				
~~(aa)~~	~~be responsible to the Council for compliance with the Act; and~~				
~~(bb)~~	~~control the manufacturing, distribution,~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~wholesaling and the sale of medical devices or IVDs.~~				
(b)	~~submit to the Registrar an application for a licence, on a form approved and provided by the Council;~~ Be submitted to the authority;		(b) be submitted to the Authority;		
(c)	~~as part of the application, provide acceptable~~ Be accompanied by documentary proof of-		(c) be accompanied by documentary proof of		
(i)	the particulars of the owner of the business;		(i) the particulars of the owner of the business;		
(ii)	the particulars of the authorised representative; ~~and~~		(ii) the particulars of the authorised representative;		
(iii)	certification ~~to a Quality Management System for medical devices and IVDs as determined by the Council;~~ certification by a conformity assessment body to		(iii) certification by a conformity assessment body to ISO 13485 in the case of an application in terms of sub-	certification by a conformity assessment body to ISO 13485 in the case of an application in terms of sub-regulation (~~1)(6)(1)~~	Error in sub-regulation reference

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	ISO 13485 in the case of an application in terms of sub-regulation (1)(a)(i) or 1 (a)(ii);		regulation (1)(6)(1) or 1(a)(ii);	~~(~~1)(a)(i) or 1(a)(ii);	
(iv)	the payment of the prescribed application fee; and		(iv) the payment of the prescribed application fee;		
(v)	any other information as may be requested by the Authority; and		(v) the physical address of the site; and		
(vi)			(vi) any other information as may be requested by the Authority; and		
~~(d)~~	~~Specify the , as determined by the Council, the medical devices or IVDs or~~	-not needed as section 22C licences do not relate to specific devices or IVDs. The specific devices or IVDs are governed by sections 14 and 15, and the regulations issued thereunder.	(d) specify the-		
~~(i)~~	~~Name, group or family name; and~~		(i) name, group or family name; and	(i) name, group or family or system name; and	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(ii)~~	~~Make and model, where applicable,~~		(ii) make and model, where applicable,		
	~~of medical devices or IVDs to be manufactured, imported, exported or distributed and sold; and~~		of medical devices to be manufactured, imported, exported and sold	of medical devices or IVDs to be manufactured, imported, exported and sold	
~~(e)~~	~~pay the application fee.~~				
(2)	~~The Registrar may give the person referred to~~ The applicant contemplated in sub-regulation (1) ~~written notice to, within a reasonable time as specified in the notice, furnish the Council with such additional documentation or information as the Council may require.~~ must appoint and designate an authorised representative who must be responsible to the Authority for compliance with the Act.		(2) The applicant contemplated in sub-regulation (1) shall appoint and designate an authorised representative who shall be responsible to the Authority for compliance with the Act.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(3)	The ~~Council~~ Authority may, where applicable, inspect the business premises specified in the application.		(3) The Authority may, where applicable, inspect the business premises specified in the application		
(4)	~~If the Council is satisfied that-~~ The Authority may issue a licence contemplated in sub-regulation (1) once the Authority is satisfied that the requirements of the Act and the regulations have been complied with and the authorised representative is able to provide certified evidence of certification to a quality management system as determined by the Authority.		(4) The Authority may issue a licence contemplated in sub-regulation (1) once the Authority is satisfied that the requirements of the Act and the regulations have been complied with and the authorised representative is able to provide certified evidence of certification to a quality management system in terms of sub-regulation (12)(1)(c)(iii), and as determined by the Authority.		
(a)	~~the person referred to in sub-regulation (1)~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~complies with the prescribed. requirements;~~				
(b)	~~the application for a licence~~				
(i)	~~to manufacture, import or export medical devices or IVDs; or~~				
(ii)	~~to act as a distributor, or~~				
(iii)	~~to act as a wholesaler of medical devices or IVDs~~ ~~complies with the prescribed requirements; and~~				
	~~the authorised representative ls able to provide certified evidence of certification to a Quality Management System as determined by Council, the Council must approve, with or without~~ ~~conditions, the application and issue the person with a license.~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(5)	The Chief Executive Officer ~~Registrar~~ must-		(5) The Chief Executive Officer shall—		
(a)	keep a separate register for each of the categories of licensees contemplated in section 22C(1)(b) of the Act; ~~referred to in sub-regulation (1)(a)(i);~~ and		(a) keep a separate register for each of the categories of licensees contemplated in section 22C(1)(b) of the Act; and		
(b)	enter the licence number, the name of the licensee and his or her physical and postal addresses, in the register contemplated in paragraph (a).		(b) enter the licence number, the name of the licensee and his or her physical and postal addresses, in the register contemplated in paragraph (a).		
(6)	~~Despite~~ Notwithstanding the period of validity of the licence, the licensee must pay the annual fee in respect of the retention of the licence. (~~for continued registration as determined by the Council.~~	-currently annual retention fee is paid/site license issued based on fees for medicines	(6) Notwithstanding the period of validity of the licence, the licensee must pay the annual fee in respect of the retention of the licence	Devices must have own fee structure	The regulatory activities, sequencing and frequency thereof and associated fees, as well as numbers of products differ significantly from medicines.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(7)	A holder of a licence in terms of sub-regulation (1) must submit to the Authority an application, on a form obtainable from the Authority, accompanied by the prescribed fee, in order to amend any of the following details of the licence:		(7) A holder of a licence in terms of sub-regulation (1) must submit to the Authority an application, on a form obtainable from the Authority, accompanied by the prescribed fee, in order to amend any of the following details of the licence:		
(a)	name of the licence holder;		(a) name of the licence holder;		
(b)	authorised representative;		(b) authorised representative;		
(c)	~~site~~ address;	× no reference to sites, address only. QMS pertains to all relevant locations for activities in scope under one management system The Act calls for legal and natural persons to apply for an establishment license, hence evidence of address, like done for	(c) physical address ~~of the site~~;	× no reference to sites, address only. QMS pertains to all relevant locations for activities in scope under one management system The Act calls for legal and natural persons to apply for an establishment license, hence evidence of address, like done for	

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		car licensing, is prudent. QMS certification covers all relevant locations for activities in scope under one management system		car licensing, is prudent. QMS certification covers all relevant locations for activities in scope under one management system	
(d)	activities provided for by the licence; or		(d) activities provided for by the licence; or		
(e)	the medical devices to be manufactured or sold	There is no authority in the Act for listing products on licences	(e) the medical devices to be manufactured or sold, as determined by the Authority.		
(8)	Following receipt of an application referred to in sub-regulation (7) the Authority may issue a new licence: Provided that-		(8) Following receipt of an application referred to in sub-regulation (7) the Authority may issue a revised licence: Provided that—		
(a)	the Authority is satisfied that the application complies with the provisions		(a) the Authority is satisfied that the application complies with the provisions of sub-		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	of sub-regulation (1) or any other conditions determined by the Authority;		regulation (1) or any other conditions determined by the Authority; and		
(b)	either-		(b) the applicable licence fee is paid.		
(i)	the original licence is returned to the Authority; or				
(ii)	an affidavit is submitted to the Authority stating that the original licence has been lost, if this is the case; and				
(c)	the applicable licence fee is paid.				
~~(7)~~(9)	~~A licensee~~ An applicant must notify the ~~Registrar~~ Authority in writing of ~~a~~ any change to any of the particulars furnished in the application contemplated in sub-regulation (1) within 30 days of such change. ~~or entered in the register, which occurs after the issue of the licence~~	-if a company has many changes occurring, this could mean that SAHPRA will be inundated with amendment submissions. The submission requirements should be in an abridged format to reduce the administrative burden.	(9) An applicant must notify the Authority in writing of any change to any of the particulars furnished in the application contemplated in sub-regulation (1) within 30 days of such change.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		Changes that are not material to the licencing conditions, should not lead to a formal licence amendment, administrative and non-material changes should be affected by means of notification			
~~(8)~~(10)	An entry into the register in terms of sub-regulation (5) which is proved to the satisfaction of the ~~Council,~~ Authority to have been made in error or through misrepresentation or in circumstances not authorised by the Act. may be removed from the register.		(10) Any entry into the register in terms of sub-regulation (5) which is proved to the satisfaction of the Authority to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.		
~~(9)~~ (11)	A person in respect of ~~whom an~~ whose entry a removal ~~has been removed~~ as contemplated in sub-regulation ~~(8)~~(10), has been made must be		(11) A person in respect of whose entry a removal as contemplated in sub-regulation (10) has been made shall be notified of such		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	notified of such ~~the~~ removal and any licence ~~a certificate~~ issued in respect of the ~~registration in question~~ regulation must be deemed ~~considered~~ to be cancelled as from the date on which notice has so been given.		removal and any licence issued in respect of this regulation shall be deemed to be cancelled as from the date on which notice has so been given.		
~~(10)~~(12)	~~The Council may, subject to sub-regulation (11), direct the Registrar to remove the name of a licensee from the register if -~~ The Chief Executive Officer may make known to the public, any information that pertains to the suspension or revocation of any licence referred to in this regulation in a manner which he or she thinks fit.		(12) The Chief Executive Officer may make known to the public any information that pertains to the suspension or revocation of any licence referred to in this regulation in a manner which he or she thinks fit.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(a)~~	~~the licensee does not comply with the Act or the conditions of a licence;~~				
~~(b)~~	~~the authorised representative fails to control the manufacturing or distribution, wholesaling or sale of the medical devices or IVDs; or~~				
~~(c)~~	~~the licensee fail& to furnish written reasons within the period stated in the notice referred to in sub-regulation (11).~~				
~~(11)~~	~~Before directing the Registrar to remove the name of a licensee from the register, the Council must-~~				
~~(a)~~	~~give notice to the licensee of its intention to remove the name of the licensee from the~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~register and to close the licensee's business; and~~				
~~(b)~~	~~invite the licensee to furnish written reasons, within 21 days of the notice, why the licensee's licence must not be removed from the register and the business closed.~~				
~~(6)~~ 14.	**PERIOD OF VALIDITY ~~OF LICENCE~~ AND RENEWAL OF LICENCE.**		**13. PERIOD OF VALIDITY AND RENEWAL OF LICENCE**		
(1)	A licence issued in terms of ~~regulation 5 is~~ section 22C(1)(b) and referred to in regulation 13 must, provided that the holder pays the applicable annual fee, be valid for a period of five ~~(5)~~ years from the date of issue.		(1) A licence issued in terms of section 22C(1)(b) and referred to in regulation 12 must, provided that the holder pays the applicable annual fee, be valid for a period of five years from the date of issue.		
(2)	A licence referred to in sub-regulation (1) may be renewed by		(2) A licence referred to in sub-regulation (1) may be renewed by		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	application to the Authority ~~Council.~~		application to the Authority.		
(3)	An application for the renewal of a licence must -		(3) An application for the renewal of a licence must—		
(a)	contain at least the information or documentation referred to in regulation 13(1)© and 13(1)(d); ~~5(1)©, as the case may be~~;		(a) contain at least the information or documentation referred to in regulation 12(1)(c) and 12(1)(d);		
(b)	be accompanied by fees contemplated in section 35(1)(xxxii) of the Act; ~~the prescribed fee;~~ and		(b) be accompanied by a prescribed fee in terms of section 35(1)(xxxii) of the Act; and		
©	be made at least 90 days before the expiry of the existing licence		(c) be made at least 90 days before the expiry of the existing licence.		
15.	**CONFORMITY ASSESSMENT BODY**	-refer to general comment 5 (q) above	**14. CONFORMITY ASSESSMENT BODY**		
(1)	The Authority must determine the criteria and standards required for recognition of a conformity assessment body.		(1) The Authority must determine the criteria and standards required for recognition of a conformity assessment body.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(2)	The criteria in sub-regulation (1) must include-		(2) The criteria in sub-regulation (1) must include—		
(a)	certification of the conformity assessment body either by SANAS or an international accreditation body; and		(a) certification of the conformity assessment body either by SANAS or an international accreditation body; and		
(b)	any other information as determined by the Authority.		(b) any other information as determined by the Authority.		
(3)	The Authority must publish the name and address of a conformity assessment body recognised by the Authority.		(3) The Authority must publish the name and physical address of a conformity assessment body recognised by the Authority.		
16.	~~REPLACEMENT, MAINTENANCE, REFURBISHMENT AND SINGLE USE OF MEDICAL DEVICES~~	DELETE whole of regulation 16, as this is covered within IMDRF principles of General Safety and Performance	**15. REPLACEMENT, MAINTENANCE, REFURBISHMENT AND SINGLE USE OF MEDICAL DEVICES**		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		Requirements (GSPR) which is found in Technical Documentation for Product Registration and QMS certification			
(1)	A person who sells an article intended specifically to replace an identical or similar integral part or component of a medical device must ensure that the article complies with specifications applicable to that medical device as defined by the ~~original~~ legal manufacturer or as determined by the Authority.	-refer to ISO 13485 clause 7.5.3, and clause 7.5.4 (installation and servicing); reprocessing, clause 8.3.4 (rework); or clause 7.5 (manufacturing)	(1) A person who sells an article intended specifically to replace an identical or similar integral part or component of a medical device must ensure that the article complies with specifications applicable to that medical device as defined by the original manufacturer or as determined by the Authority	SAMED reiterates its 2021 comments and proposals here.	
(2)	Where an article in sub-regulation (1) significantly changes the performance or safety characteristics of the medical device, the medical device must be considered to		(2) Where an article in sub-regulation (1) significantly changes the performance or safety characteristics of the medical device, the medical device shall be considered to		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	be a different medical device.		be a different medical device.		
(3)	A person who maintains a medical device must keep records of such maintenance and on request, make the records available to the Authority.		(3) A person who maintains a medical device must keep records of such maintenance and on request, make the records available to the Authority.		
(4)	A person who refurbishes a medical device must-		(4) A person who refurbishes a medical device must—		
(a)	ensure that any articles used to replace an integral part or component of the medical device are consistent with specifications applicable to that medical device as defined by the ~~original~~ legal manufacturer;		(a) ensure that any article used to replace an integral part or component of the medical device is consistent with specifications applicable to that medical device as defined by the original manufacturer;		
(b)	follow procedures as defined by the ~~original~~ legal manufacturer relating to the refurbishment of the medical device; and		(b) follow procedures as defined by the original manufacturer relating to the refurbishment of the medical device; and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(c)	keep records of such refurbishment and on request, make the records available to the Authority.		(c) keep records of such refurbishment and on request, make the records available to the Authority.		
(5)	A medical device designated by the ~~original~~ legal manufacturer or as determined by the Authority for single use only-				
(a)	must be disposed of after use; and				
(b)	may not be reprocessed.				
(6)	If the sterility of a medical device designated by the ~~original~~ legal manufacturer or as determined by the Authority for single use only, is compromised it-				
(a)	must be disposed of after use; and				
(b)	may ~~not be reprocessed.~~ only be				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	repackaged and/or resterilised if it: (i) was not used (ii) it can be done without compromising safety and performance (iii) the repackaging and / or resterilisation are scientifically justified or validated.				
			16 SINGLE USE MEDICAL DEVICE		
			(1) A medical device designated by the original manufacturer or as determined by the Authority for single use only —	Manufacturer decides number of uses, not authority (1) A medical device designated by the original manufacturer	The Authority does not determine only approves this. This is as the Authority would have no technical or scientific knowledge on the product design and therefore such designation
			(a) must be disposed of after use; and		
			(b) may not be reprocessed.		
			(2) If the sterility of a medical device designated by the original manufacturer		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			or as determined by the Authority for single use only, is compromised it		
			(a) must be disposed of before use and		
			(b) may not be reprocessed.		
~~**14.**~~ 17.	~~**DESTRUCTION OF MEDICAL DEVICES OR IVDs**~~	DELETE whole of regulation 17, as this is covered within IMDRF principles of General Safety and Performance Requirements (GSPR) which is found in Technical Documentation for Product Registration and QMS certification	**17. DESTRUCTION OF MEDICAL DEVICES**		
(1)	A medical device ~~or IVD~~ may not be disposed of into a municipal sewerage system.	-recommended wording: "A medical device may not be disposed of into a municipal sewerage system, unless appropriate disposal instructions to render said disposal mechanism safe are	(1) A medical device may only be disposed into a municipal sewerage system conditional to meeting the requirements of the National Environmental Management: Waste		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		provided on the product label and implemented by the user." Note: -this clause has massive ramifications for disinfectant users - how are they supposed to dispose of disinfectants, particular bulk-volume use items such as liquid chemical sterilants or instrument cleaners for example, if they can't pour them down a drain, which (albeit diluted) they are all currently doing. The cost implications of disposal will become prohibitive for all health facilities... The average hospital CSSD will dispose of between 5 and 25 litres of diluted instrument detergent-disinfectant on a daily basis, and	Act, 2008 (Act No. 59 of 2008), municipal by-laws regulating sewerage systems and disposal and according to the instructions provided by the original manufacturer.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		between 5 and 100 litres of chemical instrument sterilant or chemical instrument disinfectant on a monthly basis. The average dental practice will dispose of between 1 and 5 litres of diluted instrument detergent-disinfectant on a daily basis, and between 1 and 10 litres of chemical instrument sterilant or chemical instrument disinfectant on a monthly basis. This is over and above specialist disinfectant products such as suction system detergent-disinfectants, instrument maintenance lubricants (instrument milks) and instrument anti-oxidation agents (corrosion/stain removers) If they are			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		now forced to have chemical removal services to dispose of these, healthcare prices will increase significantly and or instrument reprocessing & healthcare infection control will be negatively affected when users start disposing less frequently than they should in order to avoid removal costs.			
(2)	The destruction or disposal of a medical device ~~or IVD~~, must be conducted in such a manner to ensure that the medical device cannon be salvaged or reprocessed.		(2) The destruction or disposal of a medical device must be conducted in such a manner to ensure that the medical device cannot be salvaged or reprocessed.		
(3)	A medical device which contains a medicine or scheduled substance must only be destroyed by a waste		(3) A medical device which contains a scheduled substance must only be destroyed by a waste		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).		treatment facility authorised in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).		
(4)	A medical device which contains a Schedule 5, 6, 7 or 8 substance or medicine must be destroyed in accordance with the provisions of regulation 44 of the General Regulations published in (Govemment Gazette 41064, Government Notice 859 of 25 August 2017.		(4) A medical device which contains a scheduled substance shall be destroyed in accordance with the provisions of regulation 44 of the General Regulations made in terms of the Act (Government Gazette 41064, Government Notice 859) 2017 as amended.		
(5)	The waste treatment facility must issue a certificate and maintain a record of the destruction contemplated in sub-		(5) The waste treatment facility must issue a certificate and maintain a record of the destruction contemplated in sub-		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	regulation (3) which must contain the following information:		regulation (3) which shall contain the following information:		
(a)	the name of the medical device which contains a medicine or scheduled substance, if known; or the schedule of the medicine or scheduled substance concerned;		(a) the name of the medical device which contains a scheduled substance, if known; or and the schedule of the scheduled substance concerned;		
(b)	the quantity of the medical devices destroyed;		(b) the quantity of the medical devices destroyed;		
(c)	the date of destruction of the medical device which contains a medicine or scheduled substance;		(c) the date of destruction of the medical device		
(d)	the name and designation of the person in whose presence such destruction took place; and		(d) the name and designation of the person in whose presence such destruction took place; and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(e)	any other information as determined by the Authority.		(e) any other information as determined by the Authority.		
~~16.~~ 18.	**CONDUCT OF CLINICAL TRIAL ~~AND~~ OR CLINICAL PERFORMANCE ASSESSMENT ~~INVESTIGATION~~**	-refer to general comment 5 (o) above -refer to APPENDIX B -clinical evaluation of medical devices should also be included -"Investigation" used in ISO 14155:2020 3.8 -IMDRF principles and ISO 14155 to be followed – ISO14155 is to be published as a SANS national standard - Products that are being investigated or trialled, whilst that type or category of device has bene called up, require s21 permits. There are no provisions in the regulations for s21's either to address unmet medical need,	**18. CONDUCT OF CLINICAL TRIAL OR CLINICAL PERFORMANCE ASSESSMENT**		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		or for research purposes.			
(1)	A person desiring to initiate or conduct a -		(1) A person desiring to initiate or conduct a—	Consider review. See Appendix B	
(a)	~~a~~ clinical ~~trial or clinical investigation~~ in respect of a ~~an unregistered~~ medical device;		(a) clinical trial in respect of a medical device; or		
(b)	a clinical performance assessment in respect of ~~for~~ an IVD; or		(b) clinical performance assessment in respect of an IVD,		
~~(c)~~	~~a new Intended purpose of a registered medical device or IVD,~~				
	must apply ~~to the Council~~ on ~~a~~ an application form, obtainable from the office of the Chief Executive Officer to the Authority for authorisation to conduct such a clinical trial or clinical performance assessment. ~~determined by the Council, for authorization to~~		must apply on an application form obtainable from the office of the Chief Executive Officer to the Authority for authorisation to conduct such a clinical trial or clinical performance assessment.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~conduct the clinical trial, clinical investigation, or clinical performance assessment.~~				
(2)	The application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information:		(2) The application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information:		
(a)	A ~~clinical investigation plan or~~ clinical trial or clinical performance assessment ~~for an IVD~~ protocol;	"clinical investigation plan" to remain	(a) A clinical trial or clinical performance assessment protocol;	SAMED stands by its previous comment	
(b)	an investigator's brochure containing, where applicable, relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal safety and performance clinical data ~~with the~~ about		(b) an investigator's brochure containing, where applicable, relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal safety and performance clinical data about the medical device concerned;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	medical device ~~or IVD~~ concerned;				
(c)	the Curriculum Vitae of the investigator		(c) the curriculum vitae of the investigator;		
(d)	a signed declaration by the applicant and the investigator that they are familiar with, and understand the protocol, and will, in the conduct of the clinical investigation or clinical trial, comply with Good Clinical Practice as determined by the Authority. ~~Council~~	-confirm ICH GCP or SA GCP	(d) a signed declaration by the applicant and the investigator that they are familiar with, and understand the protocol, and will, in the conduct of the clinical trial, comply with Good Clinical Practice as determined by the Authority;		
(e)	participant information form and informed consent documents or owner consent document in the case of animal trials; ~~and endorsements by an ethics committee recognised by the Council; and~~		(e) participant information form and informed consent documents in the case of human trials or owner consent document in the case of animal trials		
(f)	approval of the clinical trial by-		(f) approval of the clinical trial and clinical		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			performance assessment by--		
(i)	any health research ethics committee registered with the National Health Research Ethics Council in terms of the National Health Act, 2003 (Act No, 61 of 2003); or		(i) any health research ethics committee registered with the National Health Research Ethics Council in terms of the National Health Act, 2003 (Act No, 61 of 2003); or		
(ii)	in the case of research on animals, an Animal Ethics Committee, which must conform to SANS 10386; and		(ii) in the case of research on animals, an Animal Ethics Committee, which must conform to SANS 10386; and		
~~(f)~~(g)	the name and address of the institution /sites where the clinical trial or clinical ~~investigation~~ performance assessment will be conducted.	-include "investigation"	(g) the name and physical address of the institution where the clinical trial or clinical performance assessment will be conducted.		
(3)	The ~~clinical investigation plan,~~ clinical trial or clinical performance assessment protocol ~~for an IVD protocol~~		(3) The clinical trial or clinical performance assessment protocol referred to in sub-regulation (2)(a) must contain at least		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	referred to in sub-regulation (2)(a) must contain at least the following information:		the following information:		
(a)	The· number of human or animal subjects, as applicable, to be involved in the ~~C~~clinical ~~investigation, clinical trial or~~ clinical performance assessment ~~for an IVD;~~	-include "investigation"	(a) The number of human or animal subjects, as applicable, to be involved in the clinical trial or clinical performance assessment;		
(b)	the name of the investigator who must be-		(b) the names of all the investigators who must be-		
(i)	an appropriately qualified and competent person approved by the Authority ~~Council~~;		(i) appropriately qualified and competent persons;		
(ii)	resident in the Republic; and		(ii) resident in the Republic; and		
(iii)	in charge of the sites where clinical trials or clinical performance assessments ~~for an IVD~~ are conducted;		(iii) in charge of the sites where clinical trials or clinical performance assessments are conducted;		
(c)	The quantity of the ~~investigational~~ medical		(c) the quantity of the medical devices under		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	device(s) ~~or IVD units to be used in the clinical trial, clinical~~ under investigation to be used in the clinical trial or clinical performance assessment ~~for an IVD;~~		investigation to be used in the clinical trial or clinical performance assessment;		
(d)	information in respect of the design, manufacture and expected performance of the medical device ~~or IVD;~~ and		(d) information in respect of the design, manufacture and expected performance of the medical device;		
(e)	any other information determined by the Authority ~~Council.~~		(e) proof of current training in Good Clinical Practice of all investigators;		
			(f) in the case of trials involving human participants, proof of current, relevant and appropriate-		
			(i) study insurance for all participants undertaken by the applicant referred to in sub-regulation (1);		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			(ii) professional indemnity insurance for investigators; and	Must be professional indemnity "cover" as not all providers of such cover are "insurers" – some are mutuals, etc.	
			(g) any other information determined by the Authority.		
(4)	A ~~clinical investigation and a~~ clinical trial or a clinical performance assessment ~~for an IVD~~ must be conducted in accordance with the guidelines for good clinical practice determined by the Authority ~~Council~~.	-confirm ICH GCP or SA GCP	(4) A clinical trial or a clinical performance assessment must be conducted in accordance with the guidelines for good clinical practice determined by the Authority.		
(5)	A person may not conduct ~~a clinical investigation,~~ a clinical trial or a clinical performance assessment ~~for an IVD~~ referred to in sub-regulation (1), without the authorization of the Authority. ~~Council~~		(5) A person may not conduct a clinical trial or a clinical performance assessment referred to in sub-regulation (1), without the authorisation of the Authority.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(6)	The person conducting the ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~ must submit to the Authority ~~Council~~		(6) The person conducting the clinical trial or clinical performance assessment must submit to the Authority—		
(a)	Safety progress reports after every six months from the date when the ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~ was started, and 30 days after the completion or termination of the ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~; and	-include “clinical investigation”	(a) progress reports after every six months from the date when the clinical trial or clinical performance assessment was started, and 30 days after the completion or termination of the clinical trial or clinical performance assessment; and		
(b)	adverse event reports immediately or as soon as practically possible.		(b) adverse event reports immediately or as soon as practically possible.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(7)	The Authority ~~Council~~ may-		(7) The Authority may—		
(a)	request additional information;		(a) request additional information;		
(b)	Inspect the site of a ~~a clinical investigation,~~ clinical trial, or clinical performance assessment ~~for an IVD~~; or		(b) inspect the site of a clinical trial or clinical performance assessment; or		
(c)	withdraw the authorisation to conduct a ~~clinical Investigation,~~ clinical trial or clinical performance assessment ~~for an IVD,~~ if the Authority ~~Council~~ is of the opinion-		(c) withdraw the authorisation to conduct a clinical trial or clinical performance assessment, if the Authority is of the opinion-		
(i)	that the safety of the subjects of the ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~ is compromised; or		(i) that the safety of the subjects of the clinical trial or clinical performance assessment is compromised; or		
(ii)	that the scientific reasons for conducting the ~~clinical~~		(ii) the scientific reasons for conducting		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~investigation~~, Clinical trial or clinical performance assessment ~~for an IVD,~~ have changed.		the clinical trial or clinical performance assessment, have changed.		
(8)	(a) The following information for a medical device ~~or IVD~~ referred to in sub-regulation (1) must be provided, where applicable:		(8) The following information for a medical device referred to in sub-regulation (1) must be provided, where applicable:		
~~(i)~~ (a)	The intended purpose ~~or use~~ of the ~~investigational~~ medical device under investigation in the proposed ~~clinical investigation or~~ clinical trial or clinical performance assessment;		(a) The intended purpose of the medical device under investigation in the proposed clinical trial or clinical performance assessment;		
~~(ii)~~(b)	the populations and indications for which the ~~investigational~~ medical device under investigation is intended;		(b) the populations and indications for which the medical device under investigation is intended;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(iii)~~(c)	the name or number of the model or type, including software version and accessories, if any, to permit full identification and:		(c) the name or number of the model or type, including software version and accessories, if any, to permit full identification; and		
~~(iv)~~(d)	a description as to how traceability is to be achieved during and after the clinical trial or clinical performance assessment such as ~~investigation, (e.g.~~ by assignment of lot numbers, batch numbers or serial numbers~~);~~		(d) a description as to how traceability is to be achieved during and after the clinical trial or clinical performance assessment such as by assignment of batch numbers, or serial numbers.		
~~(b)~~ (9)	The medical device under investigation ~~or IVD~~ must-		(9) The medical device under investigation must—		
~~(i)~~(a)	where practical, be labelled with the name and address of the premises where the ~~clinical investigation,~~ clinical trial or clinical performance		(a) where practical, be labelled with the name and physical address of the premises where the clinical trial or clinical performance assessment is to be carried out; and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	assessment ~~for an IVD~~ is to be carried out and				
~~(ii)~~(b)	be labelled "for investigational use only".		(b) be labelled "for investigational use only".		
~~(9)~~(10)	The Authority ~~Council~~ may, subject to such conditions ~~as may be determined by the Council,~~ authorise the conduct of a ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD.~~		(10) The Authority may, subject to such conditions as may be determined by the Authority, authorise the conduct of a clinical trial or clinical performance assessment and may require approval in terms of section 21 of the Act.		
~~**17.**~~ 19.	~~**Adverse event reporting and**~~ **VIGILANCE** ~~**for medical devices or IVDs**~~	-refer to general comment 5 (j) above -SAHPRA to provide an electronic format for reporting and a database of transgressions -refer to Appendix C	**19. VIGILANCE**		
(1)	~~An authorised representative or~~ a holder of a certificate of registration in respect of a medical		(1) A holder of a licence in terms of section 22C(1)(b) or a holder of a		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	device ~~or IVD~~ must inform the Authority ~~Council~~, in the manner and within the time frame as determined by the Authority of any - ~~Council~~. ~~of a suspected adverse event reported to him or her, occurring as a result of the use of the medical device or IVD.~~		certificate of registration in respect of a medical device, must inform the Authority, in the manner and within the time frame as determined by the Authority, of any—		
(a)	new or existing quality, safety or performance concerns related to any medical device, including but not limited to adverse events; and		(a) new or existing quality, safety or performance concerns related to any medical device, including but not limited to adverse events; and		
(b)	risk management activities associated with paragraph (a).		(b) risk management activities associated with paragraph (a).		
(2)	An authorised representative or a holder of a licence in terms of section 22C(1)(b) or a holder of a certificate of registration referred to		(2) An authorised representative of a holder of a licence in terms of section 22C(1)(b) or a holder of a certificate of registration referred to		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	in sub-regulation (1) must - maintain or have access to records of the reports and case reports referred to in sub-regulation (1) above.		in sub-regulation (1) must maintain or have access to records of the reports and case reports referred to in sub-regulation (1) above.		
(3)	A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any-		(3) A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any—		
(a)	suspected adverse events; or		(a) suspected adverse events; or		
(b)	new or existing safety, quality or performance concerns,		(b) new or existing safety, quality or performance concerns,		
	occurring as a result of the use of any medical device.		occurring as a result of the use of any medical device.		
(4)	Any person referred to in sub-regulation (1) must-		(4) Any person referred to in sub-regulation (1) must-		
~~(a)~~	~~within the time frame determined by the Council, after receipt of the report referred to~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~in sub-regulation (1), inform the Council of the steps to be taken to address the adverse event;~~				
~~(b)~~(a)	whenever requested by the Authority ~~Council~~, conduct a concise critical analysis of the safety ~~and~~ or performance of the medical device ~~or IVD and~~ submit the results thereof to the Authority ~~Council~~ within a specified time frame; ~~and~~		(a) whenever requested by the Authority, conduct a concise critical analysis of the safety, quality or performance of the medical device submit the results thereof to the Authority within a specified time frame;		
~~(c)~~(b)	in the case where, after receipt of the results referred to in paragraph (a)~~(b)~~, the ~~Council~~ Authority determines that the medical device ~~or IVD~~ may not be safe to use, submit to the Authority ~~Council~~, if required to do so -		(b) in the case where, after receipt of the results referred to in paragraph (a), the Authority determines that the medical device may not be safe to use, submit to the Authority, if required to do so-		
(i)	case reports of all suspected or actual		(i) case reports of all suspected or actual		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~medical device~~ adverse events in respect of the medical device ~~or IVD~~;		adverse events in respect of the medical device;		
(ii)	where applicable, the ~~medical device or IVD~~ usage figures of the medical device , as well as b periodic safety update reports and performance studies; and		(ii) where applicable the usage figures of the medical device, as well as periodic safety update reports and performance studies; and		
(iii)	any other data requested by the Authority and; ~~Council~~.		(iii) any other data as requested by the Authority; and		
~~(d)~~(c)	keep and maintain or have access to records of the adverse event data in respect of ~~his or her or it's~~ the medical device~~s or IVDs.~~		(c) keep and maintain or have access to records of the adverse event data in respect of the medical device		
(5)	Sub-regulations (1), (2) and (3) apply in the case of registered and unregistered medical devices sold or used.		(5) Sub-regulations (1), (2) and (3) apply in the case of registered and unregistered medical devices sold or used.		
~~(4)~~(6)	~~Despite sub-regulation (1) or (3),~~ a user who becomes aware of an adverse event caused or suspected of being		(6) A user who becomes aware of an adverse event caused or suspected of being caused by a medical		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	caused by a medical device ~~or IVD~~ during the process of using or conducting post-marketing surveillance, must report the event to the ~~either to the licensee,~~ holder of a licence in terms of section 22C(1)(b), holder of a certificate of registration in respect of a medical device,~~the certificate of registration1 the manufacturer,~~ the authorised representative or the Authority ~~Council~~.		device during the process of using or conducting post-marketing surveillance, must report the event to the holder of a licence in terms of section 22C(1)(b), holder of a certificate of registration in respect of a medical device, the authorised representative or the Authority.		
~~(3)~~(7)	Nothing in this regulation must ~~may~~ be interpreted as prohibiting ~~a~~ any person from reporting an adverse event, safety, quality or performance concern caused or suspected of being caused by a		(7) Nothing in this regulation must be interpreted as prohibiting any person from reporting any adverse event, safety, quality or performance concern caused or suspected of being caused by a medical device.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	medical device. ~~to the Council~~				
~~25.~~ 20.	MEDICAL DEVICE THAT IS CUSTOM-MADE ~~Custom-made medical devices~~		**20. A MEDICAL DEVICE THAT IS CUSTOM-MADE**		
(1)	A ~~custom made~~ medical device that is custom made may only be manufactured, imported or exported and sold in compliance with the guidelines as determined by the Authority; ~~must be manufactured and sold in compliance with the guidelines applicable to medical devices~~.	✓-note that previously custom-made devices did not require registration. Industry would like to understand the rationale for change	(1) A medical device that is custom made may only be manufactured, imported or exported and sold in compliance with the guidelines as determined by the Authority.		
~~26.~~ 21.	**RECORD OF** CLASS D MEDICAL DEVICE, IMPLANTABLE CUSTOM-MADE MEDICAL DEVICE OR ACTIVE ~~implantable medical device and~~ **CUSTOM-MADE MEDICAL DEVICE**		**21. A MEDICAL DEVICE THAT IS CUSTOM-MADE**		
(1)	A permanent record in respect of a Class D	-if records are archived electronically or in an	(1) A permanent record in respect of a Class D		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~implantable~~ medical device, implantable custom-made medical device, long term implantable medical device or an active custom-made medical device ~~and a high-risk custom-made medical device~~ must be kept by a designated healthcare provider, ~~on the premises~~ by the health~~care institution~~ establishment ~~or healthcare professional~~ where such the medical device~~s are~~ is sold to the patient, and must contain the following information:	online format, then "on the premises" should be deleted -not all long term implants are class D, but could also be Class C	medical device, implantable custom-made medical device or an active custom-made medical device must be kept by the health establishment where such medical device is sold to the patient, and must contain the following information:		
(a)	The name and model ~~the product code~~ of the medical device used;		(a) the name and model of the medical device used;		
(b)	~~the date on which the order for the implantable or custom made medical device~~		(b) the nomenclature system code, where applicable;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~was raised;~~ the nomenclature system code, where applicable;				
~~(c)~~	~~the model number, batch number, and serial number, if applicable;~~				
~~(g)~~(c)	the name of the manufacturer of the ~~implantable or custom made~~ medical device used;~~ and~~		(c) the name of the manufacturer of the medical device used		
~~(h)~~(d)	~~information relating to the design, manufacturing and performance of the medical device including expected performance.~~	-the healthcare provider and/or health establishment will not have the design, manufacturing and performance information of the device. This is kept by the legal manufacturer of the device.			
(e)	~~the~~ batch number or serial number of the medical device used, where applicable.		(d) the batch number or serial number of the medical device used, where applicable;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(f)	~~expected life of the medical device used;~~	-the healthcare provider and/or health establishment will not have expected life of the medical device. This is kept by the legal manufacturer of the device.	(e) the expected life of the medical device used;		
(g)	the name, address and identification number of the patient;		(f) the name, identification number and physical address of the patient;		
~~(e)~~(h)	where applicable, the name of the user and, in the case of an implantable medical device, the person responsible for the implantation of the medical device;		(g) where applicable, the name of the user and, in the case of an implantable medical device, the person responsible for the implantation of the medical device;		
~~(f)~~(i)	the name and address of the health establishment;		(h) the name and physical address of the health establishment;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(j)	the name of the designated health care provider; and		(i) the name of the designated health care provider or veterinarian; and		
(k)	the date of use of the medical device.		(j) the date of use of the medical device.		
(2)	The ~~order~~ permanent record in terms of sub-regulation (1) must be retained at the ~~business address of the seller~~ of the health establishment or health care provider for a period of at least five years beyond the expected life of the medical device		(2) The permanent record in terms of sub-regulation (1) must be retained by the health establishment or health care provider or veterinarian for a period of at least five years beyond the expected life of the medical device.		
(3)	~~The manufacturer, distributor or wholesaler of Class D or implantable custom made medical devices must keep a record of Class D or implantable custom made medical devices in the form of invoices that must reflect~~ In the	-there are multiple means of keeping traceability records that could be more appropriate than invoices.	(3) In the case of a Class D medical device, implantable custom-made medical device or an active custom-made medical device a record must be kept and shall contain the following particulars:		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	case of a Class D medical device and implantable or an active custom-made medical device a record in ~~the~~ a suitable form ~~of~~ ~~invoices~~ must be kept and must contain the following particulars:				
(a)	the date of ~~transaction of every~~ sale;		(a) date of sale;		
(b)	the ~~proprietary~~ name make and model of the medical device;		(b) the name, make and model of the medical device;		
(c)	the name, and address of every purchaser;		(c) name and physical address of every purchaser;		
(d)	the quantities sold; and		(d) the quantity sold; and		
(e)	the ~~nomenclature system code,~~ batch number, or serial number, where applicable	-the nomenclature code is assigned to a family. It does not have a significant meaning to the users or handlers of medical devices. It does not help with the	(e) the nomenclature system code, batch number, or serial number, where applicable.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		traceability of devices at all.			
(4)	A record referred to in sub-regulation (3) must be kept ~~for a period of fifty years from the date of sale~~		(4) A record referred to in sub-regulation (3) must be kept-		
(a)	in the case of a Class D medical device by the holder of a licence in terms of section 22C(1)(b); or		(a) in the case of a Class D medical device by the holder of a licence in terms of section 22C(1)(b); or		
(b)	in the case of an implantable or an active custom-made medical device by the person authorised by virtue of his or her professional qualification to order the manufacture of such medical device, for a period of fifty years from the date of sale.	-retention period is impractical: replace with "for a period of at least five years beyond the expected life of the medical device" Note: For children, lawsuits can happen till they are 21. A lawsuit can also occur at any time after a problem starts, which could be at year 7 after an implant, or year 27.	(b) in the case of an implantable or an active custom-made medical device, by the person authorised by virtue of his or her professional qualification to order the manufacture of such medical device, for a period of fifty years from the date of sale.		
(5)	For the purposes of this regulation "active custom-made medical device"	-the definition given is for any active medical device and not for an	(5) For the purposes of this regulation "active custom-made medical device"		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	means any medical device for which the operation depends on a source of electrical energy or any source of power, other than that directly generated by the human body or gravity which acts by converting this energy that has been custom made for a particular user and/or patient.	active custom made device.	means any custom-made medical device for which the operation depends on a source of electrical energy or any source of power, other than that directly generated by the human body or gravity which acts by converting this energy.		
21. 22.	**ADVERTISING OF MEDICAL DEVICES ~~OR IVDs~~**	Regulation of medical device/IVDs must take into account where these products are used and how patients get accurate information about medical technology. Risk-based medical device/IVD classification is a pre- and not a post-marketing tool. Advertising poses no risk to patients, when balanced against the importance of patients	**22. ADVERTISING OF MEDICAL DEVICES**		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		having information on devices available to them for treatment. The education of patients on devices is an important aspect of health care in this sector, and advertising plays a key role. For example, patients need to have access and understand devices used in audiology, diabetes care, de-fibrillators, IUDs, etc.			
		Reword Regulation 22 per EU-MDR Article 7 – Claims: "In.... advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by: (a) ascribing functions and			There is no justification for not allowing information about medical devices, their correct use, etc. to flow freely directly to consumers. Medical devices are not medicines, where there is a health risk associated to the abuse thereof. The converse is true, the better the information, the better the choice

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		properties to the device which the device does not have; (b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; (c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; (d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out."			of the patient / consumer and the better the use thereof. It also goes against the provisions in the CPA< where the company is liable for incorrect use, or inadequate instructions. The CPA provides consumers with choice, as does the HPCSA Ethical Rules. The sale of many medical devices are regulated, i.e. even if a patient accesses information about a product, it enhances their ability to make a choice, but does not allow them to access such a product. In general, this prohibition violates the rights of freedom of commercial

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					expression, and unjustifiably limits the property rights of the entity owning the products.
~~(1)~~(1)	~~The following requirements apply to an advertisement of a medical device or IVD:~~		(1) A medical device may be advertised to a health care provider or veterinarian.		
~~(a)~~ (1)	~~Only~~ A Class A and Class B medical devices~~ and IVDs~~ may be advertised to the public ~~or a lay person.~~		(2) A Class A and Class B medical device may be advertised to the public.		
(2)	~~A Class C and Class D medical device may be advertised to health care providers: Provided that, certain Class C and Class D medical devices as determined by the Authority may be advertised to the public.~~ A Class C and Class D medical device and IVD may be advertised to	× delete Proposed revised wording as previous was ambiguous Additional note : It is recommended to provide clarity on the Class C and D products that would be authorized to advertise to the public and should be based on both risk and intended	(3) A Class C and a Class D medical device may only be advertised to the public as determined by the Authority.	Please clarify how authority will determine this?	As it stands, the amended version of this proposed regulation makes SAHPRA the legislature to decide on advertisement on an ad hoc basis, with no principles underpinning such decision-making.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	the public in accordance with its intended purpose.	purpose. Education and information about certain medical devices and IVDs could ensure that the patient or caregiver can self-manage certain elements of their care and provide a sustainable approach to primary healthcare which would in turn relieve some of the burden placed on healthcare providers. "intended purpose " means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance			

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		evaluation (Reference to the EU IVDR).			
~~(b)~~	~~despite sub-regulation (a), male or female condoms may be advertised to the public.~~				
~~(c)~~ (3)	an advertisement for a medical device ~~or IVD~~ may not contain a statement which deviates from, is in conflict with or goes beyond, -	× delete	(4) An advertisement for a medical device may not contain a statement or claim which deviates from, is in conflict with or goes beyond—		SAMED proposes adoption of the EU wording as stated above.
(a)	~~the~~ in the case of a registered medical device, evidence submitted in the application for registration of the medical device ~~or IVD~~ with regard to its safety, quality, or performance where the evidence has been-	× delete	(a) in the case of a registered medical device, evidence submitted in the application for registration of the medical device with regard to its safety, quality, or performance where the evidence has been-		
(i)	accepted by the Authority ~~Council~~ in	× delete	(i) by the Authority in respect of the medical device; and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	respect of the medical device ~~or IVD~~; and				
(ii)	incorporated into the approved instructions for use of the medical device ~~or IVD.~~	× delete	(ii) incorporated into the approved instructions for use of the medical device; or		
(b)	in the case of an unregistered medical device, the essential principles of safety and performance.	× delete	(b) in the case of an unregistered medical device, evidence available to meet the essential principles.		
(4)	An advertisement for a medical device must contain-		(5) An advertisement for a medical device must contain—		
(a)	the name of the medical device;		(a) the name of the medical device;		
(b)	the intended purpose of the medical device;		(b) the intended purpose of the medical device		
(c)	any contra-indications or warnings;	× delete	~~(c) any contra-indication or warning;~~	× delete	
(d)	In the case of a a written advertisement ~~for a medical device or IVD must contain-~~	× delete	~~(d) in the case of a written advertisement~~	× delete	
(i)	~~the name of the medical device or IVD; and~~ ~~the class of the medical device~~	× delete -the classification of the device has no significance for the user, and can be	~~(i) the class of the medical device;~~	Delete	No significance to user and can be determined from registration information.

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
		determined from the registration information.			
(ii)	the name of the license holder in terms of Section 22C(1)(b), where applicable; and	× delete	(ii) the name of the licence holder in terms of Section 22C(1)(b), where applicable; and		
~~(ii)~~(iii)	in the case of a registered medical device ~~or IVD~~, the name and address of the holder of the certificate of registration and the registration number allocated to the medical device and; ~~or IVD;~~	× delete	(iii) in the case of a registered medical device, the name and physical address of the holder of the certificate of registration and the registration number allocated to the medical device; and		
(e)	in the case of a Class C or Class D medical device, written information including at least the information referred to in regulation 7 or regulation 8, as the case may be, must be available.	× delete	(e) in the case of a Class C or Class D medical device, written information including at least the information referred to in regulation 6 or regulation 7, as the case may be, must be available to the health care provider or veterinarian.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(i)~~	~~when a Class C or Class D medical device or IVD is advertised for the first time to a prospective user, written information, which must include at least the information referred to in regulation 23 or regulation 24 as the case may be, must simultaneously be given to the person ~. whom the oral, electronic or printed advertisement is directed; and~~				
~~(ii)~~	~~when the medical device or IVD is advertised on subsequent occasions, the information must be available on request~~				
~~23.~~	~~EXHIBITION OR APPRAISAL OF MEDICAL DEVICES~~	-refer to general comment 5 (o) above	**23. EXHIBITION OR APPRAISAL OF MEDICAL DEVICES**		
~~(1)~~	~~A Medical device made available for exhibition~~	Exhibitions and appraisal of medical	(1) A Medical device made available for	SAMED stands by its previous comments in	Exhibitions and appraisal of medical

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~or demonstration may not be used for clinical purposes and must be clearly labelled "For exhibition I demonstration purposes only- Not for clinical use"-~~	devices are not clinical trials and are managed under ISO13485 clause 7.2.3 Communication. While the empowering s18B mandates that there be regulations on exhibition/appraisal, and ensures access to free supply to devices for HCPs and others to appraise it, test it, etc, the regulatory requirements for a simple demonstration and review of the use of a medical device outside of a clinical setting should be minimal	exhibition or demonstration may not be used for clinical purposes and must be clearly labelled For ***exhibition I demonstration purposes only – Not for clinical use"—***	this regard. Propose removal of this section.	devices are not clinical trials and are managed under ISO13485 clause 7.2.3 Communication. While the empowering s18B mandates that there be regulations on exhibition/appraisal, and ensures access to free supply to devices for HCPs and others to appraise it, test it, etc, the regulatory requirements for a simple demonstration and review of the use of a medical device outside of a clinical setting should be minimal
~~(a)~~	~~on the medical device itself or on the packaging of each unit; and~~		(a) on the medical device itself or on the packaging of each unit; and		
~~(b)~~	~~on the packaging of multiple medical devices,~~		(b) on the packaging of multiple medical devices.		
~~(2)~~	~~A medical device may be made available for appraisal, which~~		(2) medical device may be made available for		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~includes the use of the medical device for training or performance assessment: Provided that-~~		appraisal which may include training on the use of the medical device, provided that—		
~~(a)~~	~~the quantity supplied is limited to the quantity required for the purposes of such appraisal;~~		(a) the quantity supplied is limited to the quantity required for the purpose of such appraisal;		
~~(b)~~	~~such medical device is made available only to a health care provider that is appropriately qualified and informed in order to use or direct the use of the medical device;~~		(b) such medical device is made available only to a health care provider or veterinarian that is appropriately qualified and informed in order to use or direct the use of the medical device;		
~~(c)~~	~~the full instruction for use of the medical device is available;~~		(c) the full instruction for use of the medical device is available;		
~~(d)~~	~~a record of the:~~		(d) a record of the:		
~~(i)~~	~~name, make and model of the medical device;~~		(i) name and make of the medical device and model of the medical		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			device, applicable;		
~~(ii)~~	~~classification of the medical device as per regulation 5;~~		(ii) name of the original manufacturer of the medical device;		
~~(iii)~~	~~nomenclature system code of the medical device;~~		(iii) classification of the medical device as per regulation 4;		
~~(iv)~~	~~batch number or serial number of the medical device;~~		(iv) batch number or serial number of the medical device;		
~~(v)~~	~~control number or version number of the accessory or software as applicable;~~		(v) control number or version number of the accessory or software as applicable		
~~(vi)~~	~~name and qualification of the health care provider who conducts the appraisal;~~		(vi) name and qualification of the health care provider or veterinarian who		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			conducts the appraisal;		
~~(vii)~~	~~name of the health establishment or place where the appraisal is conducted;~~		(vii) name of the health establishment or place where the appraisal is conducted;		
~~(viii)~~	~~date of appraisal of the medical device; and~~		(viii) date of appraisal of the medical device; and		
~~(ix)~~	~~written report of the appraisal, is available; and~~		(ix) a written report of the appraisal, is available; and		
~~(e)~~	~~any adverse event experienced during the appraisal of the medical device is reported to the Authority.~~		(e) any adverse event experienced during the appraisal of the medical device is reported to the Authority.		
~~18~~	**INVESTIGATIONS**		**25. INVESTIGATIONS**		
(1)	The ~~Council~~ Authority may conduct an investigation with regard to a medical device ~~or IVO, its manufacturer,~~		The Authority may conduct an investigation with regard to a medical device if—		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~distributor or wholesaler~~ if-				
(a)	the medical device ~~or IVD~~ is recalled in South Africa or any other country;		(a) the medical device is recalled in South Africa or any other country;		
(b)	~~a medical device or IVD~~ an adverse event is reported in South Africa or any other country;		(b) an adverse event is reported in South Africa or any other country;		
(c)	the medical device ~~or IVD~~ is suspected or found not to comply with the requirements of the Act;		(c) the medical device is suspected or found not to comply with the requirements of the Act;		
(d)	there is an international alert with regard to the medical device, ~~IVD or the manufacturer of the medical device or IVD; or~~		(d) there is an international alert with regard to the medical device; or		
(e)	for any other reason, the Authority ~~Council~~		(e) for any other reason, the		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	considers it necessary to conduct an investigation on the medical device ~~or IVD.~~		Authority considers it necessary to conduct an investigation on the medical device.		
~~15~~. 25.	**METHOD OF TAKING A SAMPLES DURING INVESTIGATION, CERTIFICATE TO BE ISSUED AND REPOR TING OF ANALYSIS RESULTS**		**26. METHOD OF TAKING A SAMPLE DURING INVESTIGATION, CERTIFICATE TO BE ISSUED AND REPORTING OF RESULTS**		
~~(1)~~	~~An inspector may, take a sample, or any quantity of samples, of a medical device or IVD for purposes of testing, examination or analysis by a person suitably qualified within his or her professional scope of practice, such as a Clinical engineer, technician, or pathologist.~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(2)~~(1)	~~The sample or samples contemplated in sub-regulation (1)~~ A sample taken in terms of section 28(1)(b) of the Act must -		(1) A sample taken in terms of section 28(1)(b) of the Act must—		
(a)	be taken in the presence of the authorized representitive ~~the person who is in charge of the medical device or IVD~~, or in the absence of that person, in the presence of any witness present		(a) that person, in the presence of any witness present;		
~~(c)~~(b)	be ~~packed and sealed and~~ suitably labelled or marked ~~in such a manner as its nature may permit and~~		(b) suitably labelled or marked;		
~~(b)~~(c)	be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;		(c) be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			(d) packed, sealed or transmitted, as applicable in such a manner as its nature may permit; or		
(d)	be transmitted by any suitable means to a person referred to in section 27 of the Act. ~~suitably qualified within his or her professional scope of practice such as an analyst, clinical engineer, technician or pathologist together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.~~		(e) be transmitted by any suitable means to a person referred to in section 27 of the Act.		
~~(4)~~(2)	An inspector ~~referred to in sub-regulation (1)~~		(2) An inspector may, in terms of these		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	may, in terms of these Regulations, take a sample during a routine inspection from a holder of a licence issued in terms of section 22C(1)(b) or the holder of a certificate of registration of a medical device~~, from a manufacturer, a distributor, a wholesaler or retailer,~~ for testing, examination or analysis.		Regulations, identify and take the required sample during a routine inspection, from a holder of a licence issued in terms of section 22C(1)(b) or the holder of a certificate of registration of a medical device, for testing, examination or analysis.		
(3)	~~The suitably qualified person referred to in sub-regulation (1) must, as soon as possible after receipt of the sample, test examine or analyse the sample and report the results of the test, examlnation or analysis~~ The sample or samples in sub-regulations (1) and (2) must be		(3) Any sample in sub-regulations (1) and (2) must be accompanied by the certificate in terms of section 28(2)(a)(iii) of the Act signed by the inspector, a copy of which shall be issued to the person in sub-regulation(1)(a) by the inspector.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	accompanied by the certificate in terms of section 28(2)(a)(iii) of the Act signed by the inspector, a copy of which must be issued to the person in sub-regulation(1)(a) by the inspector.				
~~(6)~~(4)	A certificate ~~issued in terms of this regulation or a report contemplated~~ in sub-regulation (3), must be supplied ~~submitted~~ to the Chief Executive Officer ~~Registrar~~ within 7 days from the date of issue.		(4) The certificate in sub-regulation (3) shall be supplied to the Chief Executive Officer within seven days from the date of issue.		
(5)	The person authorised in terms of section 27 of the Act must, as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results of such test, examination or analysis to the Authority.		(5) The person authorised in terms of section 27 of the Act must, as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results of such test, examination or analysis to the Authority.		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
(5)	~~Despite sub-regulation (1),~~ the Authority ~~Council~~ may require a holder of a certification of registration of a medical device or a health establishment to supply the Authority ~~Council~~ with a sample of a particular medical device ~~or IVD~~ in order to test, examine or analyse the sample.		(6) The Authority may require a holder of a licence in terms of section 22C(1)(b), the holder of a certificate of registration of a medical device or a health establishment to supply the Authority with a sample of a particular medical device in order to test, examine or analyse the sample.		
(7)	In the case of a medical device where a sample cannot be taken, an onsite test, examination or analysis may be conducted by an inspector or a person authorised in terms of section 27 of the Act.		(7) In the case of a medical device where a sample cannot be taken, an onsite test, examination or analysis may be conducted by an inspector or a person authorised in terms of section 27 of the Act.		
~~20.~~ ~~26.~~	**COMPLIANCE WITH REQUIREMENTS**		**27. COMPLIANCE WITH REQUIREMENTS**		
~~(1)~~	~~A medical device or IVD must conform to the standards and specifications which~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~were furnished to the Council on the form referred to in regulation 8 and which form has been accepted by Council in respect of the medical device or IVD.~~				
~~(2)~~(1)	A medical device or IVD must conform		(1) Every medical device must comply with—		
(a)	~~The~~ Essential Principles as determined by the Authority ~~furnished to the Council with a~~		(a) the essential principles as determined by the Authority; and		
(b)	~~To~~ any declaration of conformity furnished to the Authority, with regard to such medical device. ~~referred to in regulation 8(7).~~		(b) any declaration of conformity furnished to the Authority, with regard to such medical device.		
~~(3)~~(2)	A proposed deviation ~~from~~ related to the essential principles or declaration of conformity in sub-regulation (1) must be submitted and approved as		Any proposed change or deviation related to the essential principles or declaration of conformity in sub-regulation (1) must be submitted and		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	determined by the Authority ~~accepted standards and specifications referred to in sub-regulations (1) and (2), must be submitted to the Council for prior approval.~~		approved as determined by the Authority.		
~~**27.**~~	~~**Transitional arrangements regarding unlicensed manufacturer, distributor and wholesaler**~~	-refer to general comment 5 (p) above - should not be deleted			
~~(1)~~	~~A manufacturer, distributor or wholesaler who, at the time of the commencement of these Regulations, sells medical devices or IVDs in the Republic is, subject to regulation 5, considered to be trading legally.~~				
~~(2)~~	~~The Council must issue a notice in the Gazette calling for the licensing of unlicensed~~				

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~manufacturers, distributors and wholesalers, which notice must stipulate the conditions and time periods for licensing and that, during the process of licensing, the unlicensed manufacturers, distributors and wholesalers are considered to be trading legally.~~				
~~19.~~	**OFFENCES AND PENALTIES**		**28. OFFENCES AND PENALTIES**		
(1)	A person who fails to comply with, contravenes the provisions of, or wilfully furnishes incorrect information in respect of -		(1) A person who fails to comply with, contravenes the provisions of, or wilfully furnishes incorrect information in respect of—		
(a)	regulations 3 or 4 with regard to the importation or transmission of medical devices ~~or IVDs~~;		(a) regulation 2 or 3 with regard to the importation or transmission of medical devices;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(f)~~(b)	regulation ~~22~~ 6 With regard' to the labelling of medical devices ~~or IVDs;~~		(b) regulation 5 with regard to the labelling of medical devices;		
~~(g)~~(c)	regulation ~~23~~ 7 with regard to the instructions for the use of a medical device which is not an IVD;		(c) regulation 6 with regard to the instructions for the use of a medical device which is not an IVD		
~~(h)~~(d)	regulation ~~24~~ 8 with regard to the instructions for use of an IVD~~;~~		(d) regulation 7 with regard to the instructions for use of an 1VD;		
(e)	regulation 13 with regard to the licence to manufacture, or distribute ~~or wholesale~~ medical devices;	remove “wholesaler”	(e) regulation 12 with regard to the licence to manufacture, distribute or wholesale medical devices;	SAMED stands by its comments on the inappropriateness of the “wholesaler” concept in the medical device supply chain.	
~~(c)~~(f)	regulation ~~14~~ 17 with regard to the destruction of medical devices ~~or IVDs;~~		(f) regulation 17 with regard to the destruction of medical devices;		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
~~(d)~~(g)	regulation ~~16~~ 18 with regard to the conduct of clinical trials;		(g) regulation 18 with regard to the conduct of clinical trials;		
~~(j)~~(h)	regulation ~~17~~ 19 with regard to reporting of adverse events and vigilance, ~~is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years.~~		(h) regulation 19 with regard to reporting of adverse events and vigilance;		
~~(e)~~(i)	regulation ~~21~~ 22 with regard to the advertising of medical devices ~~or IVDs;~~		(i) regulation 22 with regard to the advertising of medical devices; or		
			(j) regulation 27 with regard to the compliance with requirements,		
	is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding		is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	10 years or to both fine and imprisonment.		10 years or to both fine and imprisonment.		
(2)	A person who sells a medical device ~~or IVD~~ that has expired is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years.		(2) A person who sells a medical device that has expired is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years or to both fine and imprisonment	As above	
~~**28.**~~	~~**Transitional arrangements regarding unregistered medical devices and IVOs**~~	-refer to general comment 5 (p) above - should not be deleted as a transitional call up is still to be gazetted in accordance with a call up plan	**29. TRANSITIONAL ARRANGEMENTS REGARDING UNREGISTERED MEDICAL DEVICES**		
~~(1)~~	~~An unregistered medical device or IVD sold in the Republic at the lime of the commencement of these Regulations is, subject to regulation 8, considered to be sold legally until such time as the call-up notice~~		(1) An unregistered medical device sold in the Republic-subject to regulation 8, is considered to be sold legally until such time as the call-up notice period referred to in sub-regulation (2),		Request to accommodate appropriate transitional arrangements for implementation of the

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~period referred to in sub-regulation (2), for the medical device or IVD, has expired~~		for the medical device, has expired.		regulation and compliance with its provisions. We commend SAHPRA in the roll out of an effective regulatory framework for Medical Devices and IVDs. It is our understanding that the success of the roll out is achieved by implementing a phased approach. This approach supports compliance and enables the provision of resources by all stakeholders to put systems in place to

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					enable effective implementation of product registrations. It is recommended to include transitional arrangements to allow for this process to unfold as many systems still need to be identified, managed and supported by the Promotion of Administrative Justice Act to ensure that decisions and implementation is reasonable and achievable. The Act 101 section 35 (xliii) enables regulations

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
					relating to time frames for the consideration of applications.
~~(2)~~	~~The Council must from time to time, issue a notice in the Gazette calling for the registration of medical devices and IVDs which notice must-~~		(2) The Authority must from time to time, issue a notice in the Gazette calling for the registration of medical devices which notice must stipulate which class of medical device must be registered.		
~~(a)~~	~~stipulate which classes of medical devices and IVDs must be. registered; and~~				
~~(b)~~	~~provide for the conditions and time periods for the application for registration.~~				
~~(3)~~	~~Despite sub-regulation (1), the Council may require a medical device or IVD to~~		(3) Despite sub-regulation (1), the Authority may require a medical device to		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
	~~comply with the requirements that the Council may determine in order to ensure that the medical device or IVD meets the Essential Principles of safety and performance, determined by the Council.~~		comply with the requirements that the Authority may determine in order to ensure that the medical device meets the essential principles.		
	Regulations Relating to Medical Devices and in vitro Diagnostic Medical Devices (IVD), Government Notice No. 1515 published in Government Gazette No. 40480 of 09 December 2016 are hereby repealed				
			30. REPEAL OF LAWS		
			Regulations Relating to Medical Devices and in vitro Diagnostic Medical Devices (IVD), Government Notice No. 1515 published in Government Gazette		

	2021 suggested amendment	SAMED 2021 Comment	2023 draft regulation as published	SAMED 2023 Comment/proposed amendment	Supporting rationale
			No. 40480 of 09 December 2016 are hereby repealed.		
29.	**SHORT TITLE**		**31. SHORT TITLE**		
	These Regulations are called Regulations relating to Medical Devices, 2021 ~~and In Vitro Diagnostic Medical Devices (IVDs).~~		These Regulations are called Regulations relating to Medical Devices, Amendment 2023.		

APPENDIX A

SAMED position paper: e-IFU (Electronic Instructions for Use) for professional users of medical devices.

Electronic Instructions for Use (eIFU) mark a significant step towards embracing digital transformation in healthcare, ensuring that crucial information related to medical devices is easily accessible and up-to-date. The eIFU are defined as instructions for use[10] provided by the manufacturer in an electronically accessible format. There is a need for a universal acceptance of eIFU, and regulatory adoption that accommodates this digital shift while still ensuring access to paper IFU upon request.

It is imperative that the eIFU is presented with the device at the point of sale and/or delivery. Over the last decade, reliance on digital information has expanded astronomically. Consumers and patients, as well as healthcare professionals, increasingly turn to electronic sources for information about products. A growing number of popular consumer products are distributed without hard copy directions. The expanded use of eIFU instead of paper IFU for medical devices holds promise for a wide range of stakeholders, including patients, doctors, caregivers, and manufacturers, as well as for the environment.

Providing eIFU instead of paper IFU, regardless of the setting of use or the intended user, offers several benefits. These include increased availability, utility, interactivity, and accessibility to labeling, which help facilitate safe and effective use of the device. These benefits can improve a users' understanding of device functionalities and provide timelier updates regarding the device.

eIFUs are available whenever the user needs them, and allow for easy handling and storage, unlike paper IFU that may get lost, disposed of or outdated. eIFUs can be read prior to procedures and preparation of surgery rather than waiting for them to be delivered with the device. They create *user specific views* in different formats such as the possibility of embedded illustrations, multimedia (videos) or possibility to project the information from the e-IFUs They support legibility where users can resize the text as they find it more comfortable on their device.

In addition to these user-focused benefits, eIFU plays a pivotal role in supporting digital health innovation. For example, iteration of medical device software allows for rapid improvement, but paper IFU is not designed to accommodate modifications quickly and can be logistically challenging to provide to users. eIFU on the other hand, supports rapid iteration of innovative products, allowing manufacturers to provide timely notifications regarding modifications to software-based devices and ensuring users have the most current labeling information. eIFU can also reduce the impact on the environment (e.g., waste and paper use reduction, decrease in carbon output), deliver significant material cost

[10] The IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices defines Instructions for Use as "information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken." https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf

savings (e.g., smaller packages, lower freight costs), and reduce ethylene oxide (EtO) use.

However, to ensure that eIFU is effective and accessible to all, it's important to address the challenge of internet access, especially in rural areas. Strategies to overcome this include:

1. Ensuring the continued availability of paper IFU upon request, at no cost, to cater to those without reliable internet access. In general, paper IFU should be available upon request in a timely manner and at no cost.
2. Implementing a robust support system, such as a 24/7 hotline and mailing options for physical copies on request, to ensure that all users have access to the information they need.
3. Setting up dedicated eIFU access points in healthcare facilities, particularly in rural or remote areas.
4. Providing comprehensive training for healthcare professionals on eIFU navigation and use.

It should be noted that the internet access in South Africa is increasingly widespread, with the World Bank and Internet World Statistics[11] estimating an 63.1% internet penetration rate. This statistic reflects a promising landscape for the implementation of eIFU, indicating that a significant majority of the population has access to digital information.

Numerous countries allow for eIFU to be utilized for professional use, such as but not limited to the EU, Australia, USA, Canada, Brazil, UK, Egypt, Japan, Singapore, Turkey, Saudi Arabia, Kenya and Tanzania. There are regions such as India that permit the use of eIFU for a wide array of devices and In Vitro Diagnostics (IVDs), expanding beyond the confines of professional usage.

Given the global trend towards eIFU and its numerous benefits for healthcare professionals and users, adopting this approach in South Africa is crucial. It will ensure consistency with international standards, improve the safety and efficacy of medical device usage, and support environmental sustainability. This step will ensure South Africa keeps pace with global innovation and advancements seen in other jurisdictions of the world.

References:

**Medtech Europe paper: Why should all professional use instructions for all professional use medical devices benefit from electronic format?*
**E-IFU regulations:*

[11] Estimated internet penetration rate from Internet World Statistics which corresponds to the percentage of the total population of a given jurisdiction that uses the Internet. No adjustments are made for infants or illiteracy in the calculations https://www.internetworldstats.com/africa.htm#za

- *EU: E-IFU law 207/2012:*
- *USA: General Program Memorandum #G03-1 (MDUFMA), Dated: 31-Mar-2003*
- *Australia: eIFU for professional users of MDs (including IVDs) Guidance, V 1.0, Aug 2018:*
- *Brazil: Normative Instruction – IN No. 4, Dated: 15-Jun-2012*
- *Serbia: Official Gazette of RS", No. 105/2017, Article 93*
- *Canada: File No. 15-107097-797, 26-Jun-2015*
- *Turkey: Turkey Official Gazette 29314, Dated: 02-Apr-2015, Art.3*
- *Saudi Arabia: MDS – G10: Guidance on Labelling Requirements For Medical Devices, Dated: 18-Jan-2015*

APPENDIX B

Clinical performance: behavior of a medical device or response of the subject(s) to that medical device(including IVD) in relation to its intended use, when correctly applied to appropriate subject(s). [ISO14155:2020]
Clinical evaluation: a methodologically sound ongoing procedure to collect, appraise and analyse clinical data pertaining to a medical device or IVD and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential principles for safety and performance when using the device according to the manufacturer's Instructions for Use.
Note: In exceptional cases where an instruction for use is not required, the collection, analysis and assessment are conducted taking into account generally recognized modalities of use.
The type of clinical evaluation needed for IVDs can vary depending on the intended use and the target specimen from patients. However, there are some common tests that are usually required for IVD performance evaluation. This may include precision, reproducibility, interference from other substance, measuring interval (range and cutoff), expected clinical performance characteristics (e.g. sensitivity, specificity).
Clinical investigation: systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device.
Note: 'clinical trial' or ' clinical study' are synonymous with ' clinical investigation'.
[ISO 14155:2020]
Clinical investigations (synonymous with trials or studies) may be undertaken in South Africa or outside of South Africa. When clinical trial data is collected in South Africa, it is subject to the SAHPRA Guidelines for Clinical Investigations of Medical Devices. Trials should comply with both the International Conference on Harmonization's Note for Guidance on Good Clinical Practice and ISO 14155 regarding clinical investigation in human subjects.
Validation:
Validation ensures that quality control procedures will perform as intended by the manufacturers and that manufacturers' recommendations fit the needs of particular devices, such as discrete systems, products with built-in electronic controls, and products with "on board" chemical and/or biological controls. Information about the validated quality control procedures increases user's understanding of devices' overall quality assurance requirements so that informed choices regarding suitable control procedures can be made.
Performance assessment:
Although laboratory directors have the ultimate responsibility for determining appropriate quality control procedures for their laboratories, manufacturers of IVD medical devices are responsible for providing adequate information to users about performance of devices as well as a means to control risks and to verify performance within specifications. Thus, in practice, quality control is a shared responsibility of IVD medical device manufacturers and users.
Verification:
Lot verifications are already part of each laboratory's ISO15189 procedure for assay validation. In addition, each assay has a certificate of analysis issued by the respective manufacturer.

Verifying new reagent lot performance is a common task in the clinical laboratory. It is not only considered good laboratory practice, but also laboratory regulations and accreditation standards require the evaluation of each new reagent lot prior to use. Each new reagent lot has the potential to affect quality control (QC) material and/or patient sample performance. Multiple factors can affect performance of a new reagent lot, including changes in a critical reagent material or in stability of the reagents, reagent damage during transportation or storage, or incorrect calibration.
Assuring lot-to-lot consistency is particularly critical when an analyte is used for long-term follow-up of patients, when small changes in concentration might trigger further laboratory testing, imaging, or other clinical interventions. Reagent manufacturers have procedures in place to qualify the release of new reagent lots. The goal of the manufacturer should be to achieve correct recovery of the analyte, meaning that the assay is able to measure the analyte correctly based on a known expected concentration. Manufacturers also seek to minimize lot-to-lot variation when recovering patient samples. Unfortunately, manufacturers' processes to ensure lot-to-lot consistency vary greatly and their accessibility to patient samples sometimes is limited. Regarding the choice of samples that are tested, current approaches include the use of QC material supplied by the reagent vendors, third party QC material, in-house QC material, and patient samples.
RUO (as applied to IVDs)
A product may be an IVD device that is: in the laboratory research phase of development; or intended for use in the conduct of non-clinical laboratory research with goals other than the development of a commercial IVD product, i.e., these products are used to carry out research and are not themselves the object of the research. An IVD device labelled for RUO is thus limited to use in the conduct of laboratory research that is either related or unrelated to the development of IVDs, providing instructions for correctly using the product in a research manner and must be labelled with the following statement: "For Research Use Only. Not for use in diagnostic procedures". Labelling a product as such permits it to be used by researchers, who can evaluate usefulness for a specific diagnostic purpose.
RUO products can be also used in conducting nonclinical laboratory research with goals other than commercial IVD product development and are used in basic life science research and not intended for further clinical diagnostic use development.

APPENDIX C

Recommendation that SAHPRA refers to EU MDR Article 87 for this section.

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices made available on the market in South Africa, other than investigational devices, shall report, to the Authority, the following:

a) **any serious incident involving devices** made available in the South African market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting.

b) **any field safety corrective action** in respect of devices made available on the South African market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the South African market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

2. Manufacturers shall report **any serious incident** as referred to in point 1.(a) immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and **not later than 15 days** after they become aware of the incident.

3. In the event of a **serious public health threat** the report referred to in point 1 shall be provided immediately, and **not later than 2 days** after the manufacturer becomes aware of that threat.

4. In the event **of death or an unanticipated serious deterioration** in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but **not later than 10 days** after the date on which the manufacturer becomes aware of the serious incident.

5.Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

6. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with points 2 to 4 above.

7. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point 1.(b) in advance of the field safety corrective action being undertaken.

8. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide **periodic summary reports** instead of individual serious incident reports. The Authority and the manufacturer shall agree on the format, content and frequency of the periodic summary reporting.

9. The Authority shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the Authority suspected serious incidents referred to in point 1.(a).

10. Where the Authority obtains such reports on suspected serious incidents referred to
in point 1.(a) from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.
incident is a serious incident, it shall provide a report in accordance with points 1 to 4 above on that serious incident to the Authority.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting, it shall provide an explanatory statement. If the authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with points 1 to 4 above and require it to ensure that appropriate follow-up action is taken.

11. Trend reporting - manufacturers shall report any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices in question during a specific period as specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to above and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan.

12. The Authority may conduct their own assessments on the trend reports referred to in point 12 above and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety.

13. Analysis of serious incidents and field safety corrective actions - following the reporting of a serious incident, the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. Where necessary, this shall include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in point 14 below, as appropriate.

The manufacturer shall co-operate with the Authority during the investigations referred to above and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the Authority of such action.

14. The Authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The Authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety. Upon request by the Authority, manufacturers shall provide all documents necessary for the risk assessment.

15. The Authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, the Authority may intervene in a manufacturer's investigation or initiate an independent investigation.

16. The manufacturer shall provide a final report to the Authority setting out its findings from the investigation. The report shall set out conclusions and, where relevant, indicate corrective actions to be taken.

17. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The content of the draft field safety notice shall be submitted to the Authority for approval.

The field safety notice shall allow the correct identification of the device or devices involved. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

19. Analysis of vigilance data -the Authority shall, put in place systems and processes to actively monitor the data available, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.
Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the Authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.