SAMED
advancing patient care through MedTech

19 August 2021

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.435, Government Gazette #44593, published on 21 May 2021

for the attention of the

Director-General: Health, Private Bag X828, Pretoria, 0001
Director: Public Entities Governance, mihloti.mushwana@health.gov.za

EXECUTIVE SUMMARY

1. SAMED (the South African Medical Technology Industry Association), the **representative body** of medical device and *in-vitro* diagnostic (IVD) manufacturers, importers and distributors in the South African market, welcomes the opportunity to comment on the Draft Medical Device Regulations, as published for comment on 21 May 2021.

2. SAMED supports the promulgation of regulations that are **appropriate** for the South African market, that leverage on **international experience** and that of **recognised jurisdictions**, and which ensure speedy market access for devices, the life cycle of which can be 2 to 4 years in many instances.

3. **SAMED's comments**, as contained in this submission, are based on the differences between this revised version of the regulations, and those previously published in Government Gazette 40480 on 09 December 2016. 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 Act 101
   - a collaborative set of comments from multiple stakeholder voices across the sector

4. **Regulations to 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, and to provide 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. SAMED is concerned that, without the inclusion of these recommendations and cautions, an opportunity may be missed to finalise the best possible regulatory framework.

5. The following comments pertain to the **whole draft regulations document** and may not be specific to individual clauses:
   (a) **IVD Regulation.** IVDs, that had been part of medical device regulations in the previous version, dated 9 Dec 2016, are excluded from the regulations in some clauses and should be reinstated, where appropriate.
   (b) **Wholesale licence.** All references to wholesale licences should be removed, or, where required, in terms of the Medicines and Related Substances Act 101 of 1965 ("Act 101"), it should be made clear that this activity pertains to medicines only, in terms of SAHPRA guidance document, *16.02 Licence to act as Wholesaler Feb04 v1*. 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. The oversight of such activities is managed via the QMS and/or contractual agreements. Companies that distribute medical devices or IVDs should be able to source supplies by importing, or from local manufacturers/distributors. Inclusion of a wholesaler licence for medical devices will incentivise companies to import rather than to source locally. Wholesaling can remain in medicine regulations in line with Act 101. 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** to meet the definitions in the General Regulations for medicines. Note that the mandate of Section 22C of the Act may compel wholesaler license requirements to remain for medical devices/IVDs. As an alternative, because manufacturers / importers do not want to get a wholesaling licence as well, distribution activities could be included in a manufacturing / importing licence.
   (c) **Product Registration.**
      (i) Consideration must be given to how to handle registration of the same medical device by multiple distributors – it is redundant and inefficient for the same technical information to be submitted multiple times to the Regulator by different suppliers, and create 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) in terms of alignment and recognition. We recommend SAPHRA 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 previous regulations, 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, labelling, etc [Regulation 8 (2)]. We recommend SAPHRA maintain that Class A devices continue to be exempt. This approach would be consistent with

mature regulators. For example, the US FDA has exempted almost all Class I devices. Risk classification is best determined by the manufacturer, not the Regulator, as the manufacturer is best able to follow classification rules, as experts in the technologies under consideration.

(ii) The regulations do not make provision for a simple listing for Class A and B medical devices/IVDs. Additional oversight and accompanying escalation of regulatory costs for low risk devices is not necessarily productive in the South African context.

(iii) Re-classification of medical devices and IVDs in Europe is in accordance with MDR/IVDR following the GHTF (ref. IMDRF) classification rules. Industry recommends that South African regulations align with these rules. Changing the international classification of items in South Africa may add additional requirements which could result in limiting supply of medical devices to South Africa, and loss of access to technology for patients.

(iv) Industry recommends that STED submission (including validation, clinical trials, etc) for registration of lower risk (Class A and B) medical devices or IVDs not be required, and

(v) 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 embrace the principles of Good Regulatory Practices for the best possible outcome of engagement with stakeholders and fulfilment of their mandate to protect the public.

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.

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". This principle is also known as the "proportionality principle".Reference: Department of Monitoring and Evaluation, that ensures that all regulatory proposals make economic and social sense (http://www.dpme.gov.za/keyfocusareas/Socio%20Economic%20Impact%20Assessment%20System/Pages/default.aspx

(f) **Regulator skills and capacity.** SAMED believes that the South African Health Products Regulatory Authority (SAHPRA), with its various sub-departments, should 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 existing medicines framework, as a starting point for medical device regulation, is not recommended.

(g) **Regulator service levels.**

(i) In the 2016 regulations, the section on expedited registration was removed and has not been reinstated: this is a concern because of the short life cycle of medical technologies. SAMED asks the Regulator to pay attention to the requirement that medical devices be registered within 90 days to avoid obsolescence and barriers to access to technology for South African patients.

(ii) The regulations do not commit the Regulator to a Service Level Agreement. Industry 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. 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.

(h) **Pricing.** SAMED is concerned that international tendering remains in the regulations [Regulation 2]. Act 101, as amended, **mentions international tendering only in terms of medicines**: "(4) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions". Therefore, regulations for international tendering cannot be drafted for medical devices. Moreover, medical device pricing considerations do not belong in regulation intended to oversee quality, safety and performance. International tendering will raise questions in terms of a supplier's after-sales liability (e.g. responsibility for service, maintenance, training, surveillance, adverse event reporting, etc.)

(i) **Management Responsibility.** The responsibilities of the authorised representative, the legal manufacturer, and the holder of the certificate of registration require clarification, as some provisions may be unworkable or ambiguous [Refer to Regulation 1, Definitions; Regulation 9 (3), (6) (a) (vii); Regulation 10 (d); Regulation 11 (1) (b), (d); Regulation 13 (1) c ii, (2), (4), (7) b; Regulation 19 (2), (6)].

Internationally, two possibilities exist for the function of the authorised representative: (i) only for communication between the legal manufacturer and the regulator and (ii) as a qualified person who 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.

(l) **Labelling and Instructions for Use [Regulations 6, 7 and 8].**

(i) There is a requirement for the "name and business 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. This requirement would also disregard the obligations on SAHPRA under Environmental Waste Management legislation.

(ii) Exclude (or minimise) all regulations that require localisation. A special label/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. This could result in limiting supply of medical devices to South Africa, and loss of access to technology for patients. It will not add to the safety or performance of any medical device.

(iii) Exclude (or minimise) all regulations that require hard copy. 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 to align with internationally accepted standards created and recognised by mature regulators, and the IMDRF and add 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.

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

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

(i) Medical device clinical evaluations should also be included.

(ii) There should be clearer definition of IVD evaluation/investigation terminology and requirements. (Investigation as per ISO14155:2020)

(iii) We recommend that SAPHRA 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 clinical trials and evaluations should be adopted.

(p) **Transitional Measures.** When newly regulating a sector, SAHPRA should be cognisant of an appropriate transition period and learning curve before imposing complex and detailed regulation, i.e. take a step- wise approach.

(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 of Act 101, as amended 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

(s) **Appeals process.** Regulation 7 of the previous regulations has been deleted entirely and should be reinstated because there must be recourse when a decision from SAHPRA needs to be revisited. Section 24A in Act 101 which covers appeals is a high-level process involving recourse to an appeals committee and, failing that, the High Court, which is burdensome when there are smaller disputes to be resolved.

6. 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 has consulted widely with experts in the field of medical device regulation and representatives from industry (both locally and internationally), legal practitioners and other stakeholders, and submits the following comments on the draft "Regulations relating to medical devices" as contained in Government Notice No. 435, Government Gazette No 44593, published on 21 May 2021.

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.

Yours faithfully,

Tanya Vogt
Executive Officer
SAMED
August 2021

LEGEND
~~Strikethrough~~ = removed from previous regulations (Dec 2016)
Purple text = added to previous regulations (Dec 2016)
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

INDEX

	Requirement	Comment
1.	**DEFINITIONS**	
	In these Regulations a word or expression defined in the Act bears the meaning so assigned and unless the context otherwise indicates-	✓
"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;	✓
"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 incident, that may occur in association with the use of a medical device which	-include IVD -refer to general comment 5 (j) above -use the EU definition of adverse event
(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;	
~~**"as determined by the council"**~~	~~means as determined by the Medicines Control Council in the guidelines published in the Gazette from time to time;~~	✓
"authorized representative"	means a natural person, resident in the Republic of South Africa, who:	-refer to general comment 5 (i) above -not harmonized, replace with: **"authorised representative"** means a natural person, resident in the Republic of South Africa, who-

	Requirement	Comment
		(a) has the written mandate to represent a manufacturer or *an appointment from the local distributor* ~~or wholesaler~~ in 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 regard to the latter's obligations under that country or jurisdiction's legislation [SOURCE: GHTF/SG1/N055:2009, 5.2]
(a)	has the written mandate to represent a manufacturer, ~~importer~~, or distributor ~~or wholesaler~~, ~~retailer or service provider~~ in the Republic;	-refer to general comment 5 (b) above -remove "wholesaler"
(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"
~~(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;~~	
"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~~	✓

	Requirement	Comment
	~~"version number" by the manufacturer,~~	
"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);~~	✓
"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);	✓
"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;	✓
~~**"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 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,~~	-refer to general comment 5 (o) above - 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	means a study undertaken to establish or confirm the	-include medical device

	Requirement	Comment
assessment" ~~study of an IVD"~~	clinical performance of an IVD or medical device;	
~~"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 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~~	-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 manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices or 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 determined by the council;~~	-refer to Conformity Assessment Body in terms of product certification -refer to Certification Body (replaces the term Notified Body) in terms of QMS certification

	Requirement	Comment
~~**"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;	✓
~~**"custom made medical device"**~~ **"medical device that is custom made"**	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 virtue of professional qualifications~~;~~ and	✓
(b)	~~specifically made in accordance with~~ specific design characteristics;	✓
~~(c)~~	which is intended for the sole use of a particular user~~;~~ , and	✓
~~(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 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	-clarification that in the case of imported products, the legal manufacturer DoC will be acceptable - reference http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n40-2006-guidance-ca-principles-060626.pdf , section 5.2.2

	Requirement	Comment
	case of an imported product, the attestation of the legal manufacturer) of a manufacturer or distributor that the-	
(a)	relevant quality management systems fulfil requirements as determined by the Authority; and	✓
(b)	medical devices concerned fulfil the essential principles;	✓
"distribute"	means to -	
(a)	Import, purchase or export a medical device in its final form, wrapping and packaging; and/or	-refer to general comment 5 (i) above regarding clarification of economic operators 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
~~(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 placed on the market under the natural or legal person's own name; and~~	- 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 distribute)*
~~(b)~~	~~sells the medical device or IVD to a healthcare professional, healthcare institution, wholesaler or the user;~~	
"essential principals"	means the requirements relating to the safety and performance characteristics of medical devices and IVDs determined by the Authority ~~Council~~;	✓
"expiry date"	means the date up to which a medical device ~~or IVD~~ retains	-include IVDs Alternative definition:

	Requirement	Comment
	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;	- 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)
"family"	means a medical device ~~or IVD~~ comprising of the same type of medical device available in different models and sizes;	✓ -include IVDs
"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;	✓
"health care provider"	means a health care provider as defined in section 1 of the National Health Act, 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);	✓
"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; *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)
~~(a)~~	~~birth certificate, passport, valid driver's licence;~~	
~~(b)~~	~~South African identification document; or~~	

	Requirement	Comment
~~(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 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	✓
(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~~;	✓
(c)	replace an epithelial surface; or	✓
(d)	replace the surface of the eye by surgical intervention,	✓
"importer"	means any person established within South Africa that delivers or supplies within the Republic for dispatch to any destination outside the Republic	Added definition
"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 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;~~	✓ 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 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
"ISO 13485"	means the International Standard "Medical devices –	✓ means the International Standard "Medical devices – Quality management systems -

	Requirement	Comment
	Quality management systems - Requirements for regulatory purposes"; reference number ISO 13485;	Requirements for regulatory purposes"; reference number ISO 13485, and includes SANS13485;
"maintain"	means the-	✓ - replace the term "maintain" with the term "service" – "maintain" is an internal term in ISO13485 -include IVDs
(a)	service, repair and re-establishment of the function; or	✓
(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;	✓
~~**"IVD"** ("in vitro diagnostic")~~	~~means a medical device, whether used alone or in combination, intended 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;~~	-definition is in Act 101, no need to repeat in the Regulations
~~**"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 operations are carried out by that person himself or on his behalf by a third party and in whose name a**	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, regardless of whether these operations are carried out by that person himself or on his behalf by a third party."

	Requirement	Comment
	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;	
"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 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;~~	-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, ~~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)
"manufacturer"	means a person licensed to manufacture, import, distribute, export ~~or~~ wholesale medical devices in terms of section 22C(1)(b) of the Act;	means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and 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

	Requirement	Comment
		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: 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 -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 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).

	Requirement	Comment
~~(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~~	
~~(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 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.

	Requirement	Comment
"model"	means a number or combination of numbers or cyphers allocated to a medical device;	✓
~~**"misbranded"**~~	~~means a medical device labelling is false, 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 SAPHRA 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 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;~~	
(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 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"

	Requirement	Comment
(b)	any significant change in the safety profile or specifications of a medical device 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	
(d)	any change to the period used to establish the ~~its~~ expiry date of a medical device;	
~~**"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;	✓
~~**"original manufacturer"**~~	~~means the manufacturer responsible for the design and specification development of a medical device;~~	-replace with "legal manufacturer"
''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
~~**"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;~~	✓
"radiation"	means ~~energy in the form of electromagnetic waves or acoustical waves;~~	✓

	Requirement	Comment
(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;	✓
"refurbish"	means the substantial rebuilding, re-equipping, reworking 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 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~~	Software modifications are not refurbishing

	Requirement	Comment
	~~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 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
"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;	
"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);	✓
"SANS 10386"	means the South African National Standard "The care and use of animals for scientific purposes", reference number SANS 10386;	✓
"serial number"	means a unique number or combination of numbers or cyphers allocated to a unique medical device or unique	✓ include IVDs

	Requirement	Comment
	accessory to a medical device;	
~~**"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;~~	✓
(a)	of a medical device on an individual ; or	✓
(b)	an IVD on a sample	✓
"the Act"	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
"version number"	means a number or combination of numbers or cyphers allocated to unique software; and	✓ not limited to SW
"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 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)	-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 definition in the General Regulations

	Requirement	Comment
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
(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
(1)	A person may not import a medical device ~~or IVD~~ into the Republic except through one of the following ports of entry:	
(a)	Cape Town International Airport or harbour.	
(b)	Port Elizabeth Airport or harbour,	
(c)	King Shaka International Airport or Durban harbour, or	
(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	Include recommended text/deletion 'Original' manufacturer is the term used in s22H in the Act. It cannot be changed through a regulation.

	Requirement	Comment
	Authority for single use only may be imported by a licensed manufacturer for purposes of service, repair, refurbishing or maintenance	
(3)	A person may only import a medical device ~~or IVD~~ if that person-	✓
(a)	is licensed in terms of section 22C(1)(b) of the Act to import medical devices or ~~IVDs;~~ 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~~.	✓
4.	**Transmission of medical devices ~~or IVDs~~ through the Republic**	
(1)	Medical devices ~~and IVDs~~ that are transmitted through the Republic must-	
(a)	while stored in the Republic, be stored in a 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	✓
(b)	not be manipulated while in the bonded warehouse unless authorised by the ~~Council~~ Authority.	-consider labelling activities
(2)	A bonded warehouse referred to in sub-regulation (1) must comply with ~~the specified storage conditions determined by the Council.~~	
(a)	good distribution practice; and	✓ ISO 13485 service controls
(b)	license conditions as determined by the Authority	✓
~~11.~~ 5.	**Classification of medical devices ~~and IVDs~~**	-refer to general comment 5 (d) above
(1)	~~The following are the classes of medical devices and IVDs:~~ Medical devices are classified	-include IVDs

	Requirement	Comment
	by the Authority into the following classes:	
(a)	Class A – Low Risk	
(b)	Class B – Low-moderate Risk	
(c)	Class C – Moderate-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
(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 guidelines published from time to time.	-regulation through guidelines is not permitted. -classification should harmonize wherever possible. To clarify: Guidelines cannot CREATE law or legally binding provisions but flow 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).
~~(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, place the medical device or IVD in the higher of the risk classes.~~	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 delegation of legislative authority.
~~(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~~or IVD~~**	-include IVDs -refer to general comment 5 (l) above
~~(2)~~(1)	The label of each medical device ~~or IVD~~ must be in at least English and shall take the form of international	

	Requirement	Comment
	symbols in accordance with ISO 15223-1 and must appear -	
(a)	on the medical device ~~or IVD~~ itself, or on the packaging thereof or in electronic form; and	
~~(b)~~	~~on the packaging of each unit; and~~	
~~(c)~~ (b)	on the packaging of multiple medical devices ~~or IVDs~~ or in electronic form	
~~(1)~~ (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
(b)	product description and intended use;	
(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
(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
(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 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

	Requirement	Comment
		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). 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 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. 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

	Requirement	Comment
		relabelling/ repacking activities as per Article 16.3 of the EUMDR. In that case this information can be in a 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 any additional label does not obscure any information on the label provided by the manufacturer.* *In AUSTRALIA* *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:* *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* 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.

	Requirement	Comment
		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.
(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;	✓
~~(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;	✓
~~(j)~~ (i)	the expiry date, where applicable;	✓
(k)(j)	where there is no indication of the expiry date, the manufacturing date;	
~~(l)~~(k)	an indication of the special storage or handling conditions ~~applicable;~~	✓
~~(m)~~(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;	✓
~~(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)~~(q)	where appropriate an indication that the medical device is intended for-	✓

	Requirement	Comment
(i)	single use;	✓
(ii)	Clinical trial ~~investigation~~ or premarket clinical performance study;	✓ (investigation per ISO 14155:2020)
(iii)	non-clinical research, teaching or testing purposes;	✓
(iv)	~~presentation or demonstration purposes;~~ exhibition or appraisal purposes;	✓
(v)	in vitro diagnostic (IVD) 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
(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~~.	✓
(a)	identify the medical device as having been reprocessed; and	✓
(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)	✓
~~**7.**~~	~~**Appeal against decision of Council**~~	-refer to general comment 5 (s) above
~~(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~~	

	Requirement	Comment
	~~being notified of the decision of the Council.~~	
~~(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~~	
~~(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 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.~~	
~~(6)~~	~~The appeal committee -~~	
~~(a)~~	~~must determine the procedure for its hearings;~~	
~~(b)~~	~~may, if It considers it 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~~	
~~(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;~~	

	Requirement	Comment
~~(c)~~	~~must, 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~~	
~~(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.~~	
~~(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.~~	
~~23.~~ 7.	**Instructions for use of medical device (EXCLUDING IVD)**	-refer to general comment 5 (l) above
(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-	
(a)	appear on or be attached to or packed with each medical device, **or be available electronically as soft copy**	-the IFU is not packaged with each 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 needed for class A devices.

	Requirement	Comment
		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.
(b)	be in at least the English language;	
(c)	be in type having a minimum legibility; and	-define minimum legibility (recommend font size 6pt)
(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
~~(1)~~(3)	The instructions for use must contain the following information ~~in at least English;~~	
(a)	The name and proprietary name ~~or trade name~~ of the medical device;	-include trade name
(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
(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
(ii)	name and physical address of the original manufacturer; and	✓ legal manufacturer
(iii)	~~name and business address of the holder of the certificate of registration;~~	×
~~(c)~~(d)	where practical, the approved intended purpose	✓

	Requirement	Comment
	or use of the medical device and 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)~~(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 of accuracy claimed ~~for it);~~ in the case of a device 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)~~(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;	✓
(i)	any requirements for-	
(i)	special facilities; or	✓
(ii)	special training or qualifications of the intended user or other person;	✓
~~(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	✓

	Requirement	Comment
	and is ready to perform ~~safely and~~ 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;	✓
(ii)	identification of any consumable components and now to replace them;	✓
(iii)	information on any necessary calibration to ensure that the medical device operates property 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
~~(j)~~(k)	an indication of any special transport, storage or handling ~~condition that applies;~~ 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)~~(m)	if the medical device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterllisation;	
~~(m)~~(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?
(ii)	~~including information to identify when the medical device should no longer be reused (e.g. signs of material~~	

	Requirement	Comment
	~~degradation or the maximum number of allowable reuses);~~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-	
(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;	
~~(o)~~(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	
(ii)	the means of protecting the patient user, or ~~third-party~~ other person from unintended radiation 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-	
(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	

	Requirement	Comment
	reasonably foreseeable external influences or 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 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
(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
(vi)	precautions related to materials incorporated into the medical device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction· of the patient or user or any other person;	
~~(q)~~(r)	warnings and precautions to be taken related to the disposal of the medical	

	Requirement	Comment
	device, its accessories and the consumables used with it if any. ~~This information must cover,~~ 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;	
(ii)	environmental hazards ~~(e.g.~~ such as batteries or materials that emit potentially hazardous levels of radiation~~);~~ and	
(iii)	physical hazards ~~(e.g. from sharps);~~	
~~(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)~~(t)	the date of issue or latest revision of the instructions for use and, ~~where appropriate, an identification number; and~~	
~~(t)~~(u)	appropriate service and maintenance instructions for the medical device and associated technical equipment and ~~medical devices,~~ where applicable.	
~~24~~. 8.	**Instruction for use of IVD**	-refer to general comment 5 (l) above
(1)	The instructions for the use of an IVD device must - ~~contain the following in at least English:~~	

	Requirement	Comment
(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
(b)	be in at least the English language;	
(c)	be in type having a minimum legibility; and	-define minimum legibility
(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
(3)	The instructions for use must contain the following:	
(a)	The name ~~or trade name;~~ and proprietary name of the IVD;	-include trade name
(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)(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
(ii)	name and business address of the licensee as per regulation 13(1)(a)(i) or 13(1)(a)(ii); and	localised
(iii)	name and physical address of the original manufacturer;	✓ legal
~~(c)~~(d)	the intended purpose and use, including but not limited to-	
(i)	what is detected;	
(ii)	~~its function;~~ the function of the IVD.	
(iii)	the specific disorder, condition or risk factor of interest that ft is intended to detect, define or differentiate;	
(iv)	whether it is automated or not;	
(v)	whether it is qualitative or quantitative;	
(vi)	the type of specimens required (e.g. serum, plasma, whole blood, tissue	

	Requirement	Comment
	biopsy, urine); and	
(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)~~(f)	the intended user, as appropriate;	
~~(f)~~(g)	the test principle;	
~~(g)~~(h)	whether provided as an individual reagent or in an IVD kit with other appropriate articles, a description of -	
(i)	the reagent, calibrators and 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);~~	
(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 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;	
(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-	
(i)	information to identify such IVDs, medical devices or	

	Requirement	Comment
	equipment in order to obtain a safe combination; and	
(ii)	information on any known restrictions to combinations of ~~medical devices~~ IVDs and equipment;	
(k)	an indication of any special transport , storage and handling requirements ~~conditions that apply;~~	
(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;	
(m)	if the IVD is supplied as 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, 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;	
(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 ,	

	Requirement	Comment
	electrostatic discharge, radiation associated with diagnostic or therapeutic 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	
(iv)	precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or could result in sensitization or allergic reaction;	
(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;	
(q)	conditions for collection, handling, and preparation of the specimens;	-correction
(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
(s)	the information needed to verify whether the IVD is properly installed and is	

	Requirement	Comment
	ready to perform safely and 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;	
(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	
(iv)	methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing an IVD;	
(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;	
(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	
(x)	where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;	
(y)	where relevant reference intervals;	

	Requirement	Comment
(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;	
(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 must cover, where appropriate-	
(i)	infection or microbial hazards;	
(ii)	environmental hazards; and	
(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;	
(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	
(ee)	appropriate maintenance instructions for technical IVD 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)~~ (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	-Where applicable, submissions shall be made per product family/ group, and not necessarily for each individual medical device as indicated

	Requirement	Comment
	safety, effectiveness, classification risk, or changes the intended use	
(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. 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 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 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

	Requirement	Comment
~~(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 authorized representative in South Africa who ~~is~~ must be responsible for communication with the ~~Council~~ 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 -	
(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.
(b)	a proposed label for ~~use on~~ the medical device ~~or IVD~~, if applicable;	
(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)~~(e)	~~where applicable,~~ 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~~	-consider that certification by local CABs are not yet in place -refer to general comment 5 (q) above

	Requirement	Comment
	issued by a Conformity Assessment Body;	
(ii)	test result(s); or	
(iii)	inspection certification,	
	for the medical device for which the application is being made, issued by a conformity assessment body;	
~~(e)~~(f)	any other information as ~~the Council~~ may be required by the Authority ~~determine~~; and	
~~(f)~~(g)	the applicable application fee.	-no fee guideline for MDs released, currently using fees published for medicines
~~(4)~~(5)	The information referred to in sub-regulation ~~(3)~~(4) must ~~at least~~ be submitted in English.	
~~(5)~~(6)	The application form referred to in sub-regulation ~~(3)(a)~~ (1) must contain at least the following inflammation:	
(a)	Particulars of the prospective holder of the certificate of registration:	
(i)	Name;	
(ii)	Business Address;	
(iii)	Postal Address;	
(iv)	Telephone Number;	
(v)	Fax Number, where available;	
(vi)	e-mail address, if applicable ; and	
(vii)	contact details of the authorised representative referred to in sub-regulation ~~(2)~~ (3) and;	
(b)	Particulars of the medical device , including- ~~or IVD:~~	
(i)	~~The~~ proposed proprietary name and group or family name, make and model, where applicable;	
(ii)	intended purpose ~~or use;~~	
(iii)	Classification as per regulation 5; ~~and registration status in recognized authorities outside the~~	

	Requirement	Comment
	~~Republic, as determined by the Council, and proposed classification in the Republic;~~	
(iv)	classification and registration status with other regulatory authorities recognised by the Authority;	
~~(iv)~~(v)	nomenclature system code;	
~~(v)~~(vi)	in the case of a medical device which contains a medicine or scheduled substance, the approved name and quantity of each active ingredient or biological substance; and~~combination device, the name and quantity of the scheduled substances or biological substances;~~	
~~(vi)~~(vii)	the name and physical address of the original manufacturer.~~; and~~	
~~(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:	
(a)	A certified copy (electronic or hard copy) of the certificate of registration, market authorisation or premarket approval, where applicable;	-employ current best practice
(b)	instructions for use, where applicable;	
(c)	conditions of registration, where applicable; and	
(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	

	Requirement	Comment
	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.~~	
~~(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)~~	~~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:~~	
~~(a)~~	~~A certified copy of the certificate of registration or 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~~**	
	The medical device ~~or IVD~~ register must, in respect of a registered medical device ~~or IVD,~~ contain the following information:	
(a)	The -	
(i)	Name, ~~and~~ group or family 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

	Requirement	Comment
		scope of the devices registered, could be covered by regulations governing modifications
(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;	
(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;	
(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);	
(f)	the name and address of the	
(i)	original manufacturer(s); and	
(ii)	manufacturing facilities;	
(g)	the date of registration of the medical device ~~or IVD;~~	
(h)	the conditions of registration of the medical device ~~or IVD;~~	
(i)	the class of medical device ~~or IVD;~~ and	
(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	
~~(1)~~	~~A holder of a certificate of registration may submit to the Registrar an application on a form, as determined by the Council, to amend an~~	

	Requirement	Comment
	~~entry made In the medical devices or IVDs register with regard to a particular medical device or IVD.~~	
~~(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;~~	
(b)	the name of ~~and~~ the holder of the certificate of registration and the authorised representative;	
(c)	business address of the holder 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)~~(e)	the details of the amendment applied for;	
~~(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 ~~determined by the Council.~~	
(2)	Where a new certificate is issued in terms of section 15A(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.

	Requirement	Comment
(b)	~~if the original certificate of registration is lost, an affidavit must be submitted to the Authority confirming 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 case of combination medical 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**	
	A certificate of registration for a medical device as	Remove from Annexure 1 “original manufacturer” – this is a subcontracted process covered under

	Requirement	Comment
	contemplated in section 15(3) of the Act must be in a form substantially similar to the form contained in Annexure 1.	ISO13485 certification – 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".
~~**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 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 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-	
(a)	~~prior to commencing business~~ be made on an electronic format provided	-implement appropriate technology at SAHPRA

	Requirement	Comment
	by~~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;	
(ii)	to distribute a medical device, which may include the distribution, import or export of a medical device; or	
~~(iii)~~	~~to wholesale a medical device;~~	-refer to general comment 5 (b) above
~~(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, 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;	
(c)	~~as part of the application, provide acceptable~~ Be accompanied by documentary proof of-	
(i)	the particulars of the owner of the business;	
(ii)	the particulars of the authorised representative; ~~and~~	

	Requirement	Comment
(iii)	certification ~~to a Quality Management System for medical devices and IVDs as determined by the Council;~~ certification by a conformity assessment body to ISO 13485 in the case of an application in terms of sub-regulation (1)(a)(i) or 1 (a)(ii);	
(iv)	the payment of the prescribed application fee; and	
(v)	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.
~~(i)~~	~~Name, group or family name; and~~	
~~(ii)~~	~~Make and model, where applicable,~~	
	~~of medical devices or IVDs to be manufactured, imported, exported or distributed and sold; and~~	
~~(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.	
(3)	The ~~Council~~ Authority may, where applicable, inspect the business premises specified in the application.	
(4)	~~If the Council is satisfied that~~ The Authority may issue a	

	Requirement	Comment
	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.	
(a)	~~the person referred to in sub-regulation (1) 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 is 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.~~	
(5)	The Chief Executive Officer ~~Registrar~~ must-	
(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	
(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).	

	Requirement	Comment
(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
(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;	
(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 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	
(e)	the medical devices to be manufactured or sold	There is no authority in the Act for listing products on licences
(8)	Following receipt of an application referred to in sub-regulation (7) the Authority may issue a new licence: Provided that-	
(a)	the Authority is satisfied that the application complies with the provisions of sub-regulation (1) or any other conditions determined by the Authority;	
(b)	either-	
(i)	the original licence is returned to the Authority; or	
(ii)	an affidavit is submitted to the Authority stating that the	

	Requirement	Comment
	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. 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.	
~~(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 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.	
~~(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	

	Requirement	Comment
	this regulation in a manner which he or she thinks fit.	
~~(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 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.**	
(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.	
(2)	A licence referred to in sub-regulation (1) may be renewed by application to the Authority ~~Council.~~	
(3)	An application for the renewal of a licence must -	

	Requirement	Comment
(a)	contain at least the information or documentation referred to in regulation 13(1)(c) and 13(1)(d); ~~5(1)(c), as the case may be~~;	
(b)	be accompanied by fees contemplated in section 35(1)(xxxii) of the Act; ~~the prescribed fee;~~ and	
(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
(1)	The Authority must determine the criteria and standards required for recognition of a conformity assessment body.	
(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	
(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.	
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 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	-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)

	Requirement	Comment
	determined by the Authority.	
(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 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.	
(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;	
(b)	follow procedures as defined by the ~~original~~ legal manufacturer relating to the refurbishment of the medical device; and	
(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	

	Requirement	Comment
(b)	may ~~not be reprocessed~~. only be 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.	
~~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
(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 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 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 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

	Requirement	Comment
		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.	
(3)	A medical device which contains a medicine or scheduled substance must only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste 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.	
(5)	The waste treatment facility must issue a certificate and maintain a record of the destruction contemplated in sub-regulation (3) which must 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;	
(b)	the quantity of the medical devices destroyed;	
(c)	the date of destruction of the medical device which contains a medicine or scheduled substance;	

	Requirement	Comment
(d)	the name and designation of the person in whose presence such destruction took place; and	
(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, or for research purposes.
(1)	A person desiring to initiate or conduct a -	
(a)	~~a~~ clinical ~~trial or clinical investigation~~ in respect of a ~~an unregistered~~ medical device;	
(b)	a clinical performance assessment in respect of ~~for~~ an IVD; or	
~~(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 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	

	Requirement	Comment
	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
(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 medical device ~~or IVD~~ concerned;	
(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
(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~~	
(f)	approval of the clinical trial 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	
(ii)	in the case of research on animals, an Animal Ethics	

	Requirement	Comment
	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”
(3)	The ~~clinical investigation plan,~~ clinical trial or clinical performance assessment protocol ~~for an IVD protocol~~ referred to in sub-regulation (2)(a) must contain at least 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”
(b)	the name of the investigator who must be-	
(i)	an appropriately qualified and competent person approved by the Authority ~~Council~~;	
(ii)	resident in the Republic; and	
(iii)	in charge of the sites where clinical trials or clinical performance assessments ~~for an IVD~~ are conducted;	
(c)	The quantity of the ~~investigational~~ medical 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;~~	
(d)	information in respect of the design, manufacture and expected performance of the medical device ~~or IVD;~~ and	
(e)	any other information determined by the Authority ~~Council.~~	

	Requirement	Comment
(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
(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~~	
(6)	The person conducting the ~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~ must submit to the Authority ~~Council~~	
(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”
(b)	adverse event reports immediately or as soon as practically possible.	
(7)	The Authority ~~Council~~ may-	
(a)	request additional information;	
(b)	Inspect the site of a ~~a clinical investigation,~~ clinical trial, or clinical performance assessment ~~for an IVD~~; or	
(c)	withdraw the authorisation to conduct a ~~clinical Investigation,~~ clinical trial or clinical performance assessment ~~for an IVD,~~ if the	

	Requirement	Comment
	Authority ~~Council~~ 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	
(ii)	that the scientific reasons for conducting the ~~clinical investigation~~, Clinical trial or clinical performance assessment ~~for an IVD,~~ have changed.	
(8)	(a) The following information for a medical device ~~or IVD~~ 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;	
~~(ii)~~(b)	the populations and indications for which the ~~investigational~~ medical device under investigation is intended;	
~~(iii)~~(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~~);~~	
~~(b)~~ (9)	The medical device under investigation ~~or IVD~~ must-	
~~(i)~~(a)	where practical, be labelled with the name and address of the premises where the	

	Requirement	Comment
	~~clinical investigation,~~ clinical trial or clinical performance assessment ~~for an IVD~~ is to be carried out and	
~~(ii)~~(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.~~	
~~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
(1)	~~An authorised representative or~~ a holder of a certificate of registration in respect of a medical 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.~~	
(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).	
(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 in sub-regulation (1) must - maintain or have access to records of the reports and case reports	

	Requirement	Comment
	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-	
(a)	suspected adverse events; or	
(b)	new or existing safety, quality or performance concerns, occurring as a result of the use of any medical device.	
(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 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~~	
~~(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 -	
(i)	case reports of all suspected or actual ~~medical device~~ adverse events in respect of the medical device ~~or IVD~~;	
(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	

	Requirement	Comment
(iii)	any other data requested by the Authority and; ~~Council~~.	
~~(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.~~	
(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 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~~.	
~~(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 medical device. ~~to the Council~~	
~~25.~~ 20.	MEDICAL DEVICE THAT IS CUSTOM-MADE ~~Custom made medical devices~~	
(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~~	✓-note that previously custom-made devices did not require registration. Industry would like to understand the rationale for change

	Requirement	Comment
	~~manufactured and sold in compliance with the guidelines applicable to medical devices~~.	
~~26.~~ 21.	**RECORD OF CLASS D MEDICAL DEVICE, IMPLANTABLE CUSTOM-MADE MEDICAL DEVICE OR ACTIVE ~~implantable medical device and~~ CUSTOM-MADE MEDICAL DEVICE**	
(1)	A permanent record in respect of a Class D ~~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:	-if records are archived electronically or in an online format, then "on the premises" should be deleted -not all long term implants are class D, but could also be Class C
(a)	The name and model ~~the product code~~ of the medical device used;	
(b)	~~the date on which the order for the implantable or custom made medical device 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~~	
~~(h)~~(d)	~~information relating to the design, manufacturing and performance of the medical~~	-the healthcare provider and/or health establishment will not have the design, manufacturing and performance information of the

	Requirement	Comment
	~~device including expected performance.~~	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.	
(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.
(g)	the name, address and identification number 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;	
~~(f)~~(i)	the name and address of the health establishment;	
(j)	the name of the designated health care provider; and	
(k)	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	
(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 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~~	-there are multiple means of keeping traceability records that could be more appropriate than invoices.

	Requirement	Comment
	must be kept and must contain the following particulars:	
(a)	the date of ~~transaction of every~~ sale;	
(b)	the ~~proprietary~~ name make and model of the medical device;	
(c)	the name, and address of every purchaser;	
(d)	the quantities 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 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~~	
(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.
(5)	For the purposes of this regulation "active custom-made medical device" 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.	-the definition given is for any active medical device and not for an active custom made device.
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

	Requirement	Comment
		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 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 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."
~~(1)~~	~~The following requirements apply to an advertisement of a medical device or IVD:~~	
~~(a)~~ (1)	~~Only~~ A Class A and Class B medical device~~s and IVDs~~ may be advertised to the public ~~or a lay person.~~	
(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 the public in accordance with its intended purpose.	× 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 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

	Requirement	Comment
		use or in promotional or sales materials or statements or as specified by the manufacturer in the performance 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
(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
(i)	accepted by the Authority ~~Council~~ in respect of the medical device ~~or IVD~~; and	× delete
(ii)	incorporated into the approved instructions for use of the medical device ~~or IVD.~~	× delete
(b)	in the case of an unregistered medical device, the essential principles of safety and performance.	× delete
(4)	An advertisement for a medical device must contain-	
(a)	the name of the medical device;	
(b)	the intended purpose of the medical device;	
(c)	any contra-indications or warnings;	× delete
(d)	In the case of a a written advertisement ~~for a medical device or IVD must contain-~~	× 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 determined from the registration information.

	Requirement	Comment
(ii)	the name of the license holder in terms of Section 22C(1)(b), where applicable; and	× delete
~~(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
(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
~~(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
~~(1)~~	~~A Medical device made available for 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"-~~	Exhibitions and appraisal of medical 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

	Requirement	Comment
~~(a)~~	~~on the medical device itself or on the packaging of each unit; and~~	
~~(b)~~	~~on the packaging of multiple medical devices,~~	
~~(2)~~	~~A medical device may be made available for appraisal, which includes the use of the medical device for training or performance assessment: Provided that-~~	
~~(a)~~	~~the quantity supplied is limited to the quantity required for the purposes 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;~~	
~~(c)~~	~~the full instruction for use of the medical device is available;~~	
~~(d)~~	~~a record of the:~~	
~~(i)~~	~~name, make and model of the medical device;~~	
~~(ii)~~	~~classification of the medical device as per regulation 5;~~	
~~(iii)~~	~~nomenclature system code 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;~~	
~~(vi)~~	~~name and qualification of the health care provider who conducts the appraisal;~~	
~~(vii)~~	~~name of the health establishment or place where the appraisal is conducted;~~	
~~(viii)~~	~~date of appraisal of the medical device; and~~	
~~(ix)~~	~~written report of the appraisal, is available; and~~	

	Requirement	Comment
~~(e)~~	~~any adverse event experienced during the appraisal of the medical device is reported to the Authority.~~	
~~18.~~ 24.	**INVESTIGATIONS**	
(1)	The ~~Council~~ Authority may conduct an investigation with regard to a medical device ~~or IVO, its manufacturer, distributor or wholesaler~~ if-	
(a)	the medical device ~~or IVD~~ is recalled in South Africa or any other country;	
(b)	~~a medical device or IVO~~ 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;	
(d)	there is an international alert with regard to the medical device, ~~IVD or the manufacturer of the medical device or IVD; or~~	
(e)	for any other reason, the Authority ~~Council~~ considers it necessary to conduct an investigation on the medical device ~~or IVD.~~	
~~15.~~ 25.	**METHOD OF TAKING SAMPLES DURING INVESTIGATION, CERTIFICATE TO BE ISSUED AND REPORTING OF ANALYSIS 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.~~	

	Requirement	Comment
~~(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 -	Recommend a risk based approach to testing. Testing every single device and IVD would significantly delay access to treatment and eat away precious shelf life/expiry dating. As an alternative would recommend the manufacturer be allowed to provide an attestation as to the quality and performance of the MD/IVD.
(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	
~~(c)~~(b)	be ~~packed and sealed and~~ suitably labelled or marked ~~in such a manner as its nature may permit and~~	
~~(b)~~(c)	be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;	
(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.~~	
~~(4)~~(2)	An inspector ~~referred to in sub-regulation (1)~~ 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,~~	

	Requirement	Comment
	~~a distributor, a wholesaler or retailer,~~ 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 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.	
(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)	~~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.	
(7)	In the case of a medical device where a sample	

	Requirement	Comment
	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**	
~~(1)~~	~~A medical device or IVD must conform to the standards and specifications which 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	
(a)	~~The~~ Essential Principles as determined by the Authority ~~furnished to the Council with a~~	
(b)	~~To~~ any declaration of conformity furnished to the Authority, with regard to such medical device. ~~referred to in regulation 8(7).~~	
~~(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 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.~~	
~~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~~	

	Requirement	Comment
	~~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 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.~~ 27.	**OFFENCES AND PENALTIES**	
(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~~;	
~~(f)~~(b)	regulation ~~22~~ 6 With regard' to the labelling of medical devices ~~or IVDs;~~	
~~(g)~~(c)	regulation ~~23~~ 7 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~~;~~	
(e)	regulation 13 with regard to the licence to manufacture, or distribute ~~or wholesale~~ medical devices;	remove “wholesaler”
~~(c)~~(f)	regulation ~~14~~ 17 with regard to the destruction of medical devices ~~or IVDs;~~	
~~(d)~~(g)	regulation ~~16~~ 18 with regard to the conduct of clinical trials;	

	Requirement	Comment
~~(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.~~	
~~(e)~~(i)	regulation ~~21~~ 22 with regard to the advertising of medical devices ~~or IVDs;~~	
	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.	
(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.	
~~**28.**~~	~~**Transitional arrangements regarding unregistered medical devices and IVDs**~~	-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
~~(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 period referred to in sub-regulation (2), for the medical device or IVD, has expired~~	
~~(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-~~	
~~(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.~~	

	Requirement	Comment
~~(3)~~	~~Despite sub-regulation (1), the Council may require a medical device or IVD to 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.~~	
	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	
29.	**SHORT TITLE**	
	These Regulations are called Regulations relating to Medical Devices, 2021 ~~and In Vitro Diagnostic Medical Devices (IVDs).~~	

APPENDIX A

Why should the professional (non-lay user) receive electronic IFUs?

1. Professional users are expected to have access to internet, given its widespread use by businesses of all kinds.
2. Professional users have specific training in their medical discipline as a foundation to the use of medical devices.
3. Use of e-IFU has been over 15 years in the US and other major markets with a broader scope of medical devices using e-IFU. No new risk or issues have emerged challenging the e-IFU success.
4. Use of e-IFU is a practice in the last 5 years for high risk devices under the scope of 207/2012 regulation.

Benefits for Users

- UP-TO-DATE INFORMATION
  - e-IFUs provided on the internet are always the most current.
  - A paper IFU originally received with the device may be superseded by a new version which may not reach the customer unless a new device is ordered.

- INCREASED AVAILABLITY
    - e-IFUs on the internet are available whenever the user needs them, and they will enable easy handling and opening, especially in hospitals were paper IFUs are likely to be disposed of, get lost or become outdated.
    - e-IFUs can be read prior to procedures and preparation of surgery rather than waiting for them to be delivered with the device.

- INCREASED UTILITY
    - e-IFUs are searchable, which reduces the time to find specific information.
    - 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 allow for easy handling and storage, unlike paper IFU that may get lost, disposed of or outdated.
    - legibility where users can resize the text as they find it more comfortable on their device.

- ENHANCED ACCESSIBILITY
    - Their digital nature provides users with more language options
    - e-IFUs can be updated easily, which will ensure the users' instant access to the most up to date version.

- REDUCE CARBON FOOTPRINT
    - eliminating paper IFUs from each sales package both reduces paper waste from the IFU and at the same time reduces the shipping weight for each product.
    - They are likely to encourage manufacturers to use smaller sales package sizes, further reducing waste and allowing more storage space in the hospitals.
    - They facilitate compliance with the EU waste directive 2008/98/CE.
- POTENTIAL COST AND PAPER WASTE SAVING
- PORTABILITY

  Some e-IFUs support mobile platforms; these e-SFUs are portable and can be assessed from any connected mobile device wherever the user is.

Numerous countries allow for Electronic IFU to be utilized for professional use , such as, but not limited to. Australia, USA, Canada, Saudi Arabia, Turkey, Brazil, Serbia.

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.

IFUs are not always required or available for class A devices. U MDR Article 7(2) also alerts to IFUs not always needed for class A devices.

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.