

Metrics that matter

4 Code hotline cases received and

members

10 Code advisory opinions provided

YES 4 Youth jobs

29

63

providing Public Sector Debt statistics



## **CONTENTS**

<u>Chairperson's report</u>	3
From an industry association to an Institution for Collaboration	4
SAMED's ESG-centred future-forward strategy	5
<u>Increasing the value of SAMED membership</u>	6
Executive Officer's report	7
SAMED insights	8
Solving a billion-Rand government debt problem	10
Addressing other reimbursement matters	12
Compliance and regulatory report	13
Advocacy, networking, events and public relations	16
D <u>versity, inclusion and localisation</u>	18
<u>Financial and governance report</u>	22
SAMED board members	23
SAMED committees + secretariat	25
SAMED membership	26
O'MED MEMBERSHIP	
	27
<u>Contact us</u>	21



### **Chairperson's report**



As the 2025 SAMED Chairperson, it is my honour to acknowledge SAMED's incredible 40th birthday milestone and to pay homage to my predecessors and the many colleagues and members who were part of our Association's journey.

As humans, we grow up observing and celebrating how we change each year. I believe that the same applies to an industry collective like SAMED where many exemplary individuals from different branches of our medtech sector and beyond worked together to define, defend, develop and realise the incalculable value of medtech in saving and improving lives.

Way back in 1985, the then Registrar of Medicines, Johan Schlebusch advised that Act 101 was to be amended to include medical devices into the regulatory framework. Dr Roger Balding of Johnson & Johnson convened a meeting of local manufacturers to discuss the implications of such legislation, and it was decided to form SAMED – the South African Medical Device Industry Manufacturers' Association.

The early objectives of the Association were to engage with the regulatory authorities on impending registration of devices.

Our founding member forefathers were: Brittan Healthcare Group; Browning Medical cc; Marcus Medical (Pty) Ltd; Orthomedics (Pty) Ltd; Safmed (Pty) Ltd; Smith & Nephew (Pty) Ltd; Southern Implants (Pty) Ltd.



The Association membership was restricted to local manufacturers for the initial seven years. Multinationals were excluded as they were de facto well advanced regarding regulatory compliance. In 1990 the proposed changes to Act 101 were released and SAMED objected vehemently as the intent was merely to add the words 'medical devices' to legislation that dealt with pharmaceutical products. Since it was not created for medical devices, it would have been impossible for any device company to comply with such irrelevant legislation.

Due to SAMED's staying power and incredible efforts over four decades, we finally have medical device-specific regulations and SAMED continues to advocate that these be harmonised, fit-for-purpose and that they keep up with the times.



Because who would have known 40 years ago that artificial intelligence would today be enhancing diagnostics? Could we have foreseen remote monitoring technology transforming chronic disease management and telemedicine bringing consultations with HCPs to people who until recently might not have had access to healthcare?

Together, we have identified, developed, provided and shared expertise, research and resources with medtech suppliers, policy makers, funders, regulators, healthcare professionals (HCPs) and South African patients. This legacy has allowed SAMED to gain perspective and harness learnings and relationships to ensure that we can confidently look towards a prosperous future for the medtech sector and its vital role in patient care.

# From an industry association to an Institution for Collaboration

The high regard for SAMED in the market is reflected by the many local and international entities that approach SAMED for advice and assistance and shows that South Africa is an enticing place to be for the medtech industry. Despite its headwinds, South Africa provides one of the best routes into Africa.

In recognition of how SAMED's role has expanded from primarily fighting for the vital conditions for a functioning medtech industry to holistically impacting the health system and socio-economic transformation, this year the board proclaimed SAMED as an Institute for Collaboration (IFC).

The progression is truly an exciting demonstration of our elevated voice and the ability to influence South Africa's broad trajectory.

SAMED functions as an IFC which relies on partnerships to achieve its mission to serve as the collective voice of the medtech industry. A crucial aspect of this function is to empower member companies with information and tools to help them navigate through the evolving regulatory and healthcare landscape.

SAMED's roles encompass shaping and enabling efficient industry policy and regulation, supporting its members and their commercial goals and addressing macroeconomic, regulatory and competitive challenges.

As SAMED turns 40, we ought to note significant dynamics that are part of today's context and tomorrow's trajectory for the medtech sector.

South Africa and the African continent are at the same time home to recognised healthcare centres of excellence and some of the most unequal and under-served health systems worldwide.

With her youthful population, Africa can rapidly adopt and optimise digitisation and other new technologies to improve healthcare, as well as other ESG (environment, social, governance) goals and indicators.





In addition, a fundamental common spirit of togetherness – in South Africa expressed as uBuntu – provides a foundation to unite and amplify the value that our diverse businesses and services bring to each patient across vastly different healthcare settings.

# SAMED's ESG-centred future-forward strategy

Hence, I am confident SAMED's strategy which is defined in the context of ESG and led by the assigned board members can deliver on these objectives.

The environmental work-stream concentrates on advancing the objectives of the MEDTECH Master Plan as a blueprint for growth, innovation and sustainability of the sector and enabling a constructive regulatory environment. Both points require a nuanced yet persistent engagement with South African Health Products Regulatory Authority (SAHPRA) and the Department of Trade Industry Competition (the dtic) to ensure that global best practices are adopted and that they support stakeholders and the growth of the industry. SAMED, together with other trade associations, is co-funding the MEDTECH Master Plan Project Coordinator Vic van Vuuren.

Furthermore, the workstream is getting immersed into our sector's carbon footprint and the other rising environmental sustainability priorities. Multinational member companies that must report on these indicators are ahead of our other members and SAMED is developing ways to support our entire member base in embracing these necessary changes.

The social work-stream will drive SAMED's mission to foster a more inclusive, representative and impactful medtech sector.

Its primary focus is to enhance SAMED's visibility and influence power through strategic, high-impact public relations, while embedding social transformation at the core of the industry's growth. Key to the success is understanding the different generations that make up our stakeholder constituency that ranges from Baby Boomers to Gen Zs. They consume information and data differently. We need to be agile and nimble in the development and use of information technology to relate to them as well as provide insights to our members.

We will further harness the Women Empowerment Index and YES 4 YOUTH partnership to collectively promote gender equality, youth inclusion and ultimately, the sustainable transformation of the sector. I can assure you that this is not only the right thing to do, but these initiatives are critical in opening and sustaining constructive dialogue with many key stakeholders.

In addition, the work-stream will continue to support SAMED members with ongoing information sessions on key topics including ethics and legislative changes like the Employment Equity Act and the deployment of sectoral targets.







For the *governance work-stream*, the implementation of NHI presents both a significant opportunity and a challenge for the medtech sector. The team continues to proactively engage with stakeholders to ensure that the rollout of NHI supports long-term viability and sustainability of our industry. Supporting members and government to resolve the *outstanding payments* challenge is taking place within this context.

### Increasing the value of SAMED membership

Throughout the past year, our members have dealt with several complex yet interrelated policy and market dynamics. Each of our strategic topics demands a deep understanding of the landscape and thorough, ongoing engagement, both internally as well as externally with government, private and non-profit stakeholders. Addressing them firstly requires being proactive.







As our Executive Officer Tanya highlights in her video in this report, we can sit by and have things happen to us – but that's not how we act together or get the most of our membership. Or we can drive the conversation. That means that internally, in our SAMED community that acts as a serious and impactful institution for collaboration, we must participate, argue, decide, provide data, skills, time and more.

I call on my SAMED peers and the entire SAMED family to look beyond what is urgent on our daily to-do list and work on what is material and important for our progress and sustainability.

#### In conclusion

Thank you firstly to our member companies – your membership sustains SAMED as well as access to medtech products and services needed by the health system and South African patients. Thank you to the SAMED board, whose guidance and expertise have been invaluable – I truly value your time and support. I also extend my appreciation to the SAMED team. Linda, Alwi, Ntokozo, Emily, Ntombikayise, Nomthi and our knowledgeable and committed EO Tanya. This year's achievements would have been impossible without your hard work, education and passion for the industry. We thank you for your unwavering commitment to the industry and our members.

Scott de Oliveira CHAIRPERSON



## **Executive Officer's report**



I'm extremely proud to contribute my report to SAMED's 40th anniversary annual report.

The SAMED that we see in 2025 is a grown up, established Institute for Collaboration and I believe our theme, SAMED at 40: Breaking Barriers for Inclusive, Innovative and Impactful Medtech as reflected in this publication illustrates our endurance, unity in purpose and contribution of our sector to healthcare.

To say that SAMED of today is vastly different to SAMED in its inception year 1985 and even to the one I joined in 2006 is to state the obvious. I believe that many incredible leaders that we had along the way have been instrumental in getting us to this milestone.

I want to remember and make mention of those who have played consequential roles in SAMED and in my development. We cannot understate the value that both men and women leaders bring to our growth and help empower us.

The inaugural chair in 1985 was Andre du Plessis followed by Frans Erasmus and then Rob Millar who has been with SAMED since its earliest days, serving on the board, both as a chairperson and treasurer and who played an instrumental role in the development of our Code of Marketing and Business Practice. For his invaluable service to SAMED, last year Rob became our first lifelong Honorary Member.

## How we broke and continue breaking barriers

SAMED's 40th anniversary theme, Breaking Barriers – Inclusive, Innovative and Impactful Medtech, encapsulates essential messages and themes. Breaking Barriers is a rallying call to identify and overcome systemic and operational challenges that constitute many of the pain points of SAMED members – such as the need for robust and relevant regulations as well as procurement and reimbursement difficulties in both the public and private health sectors.

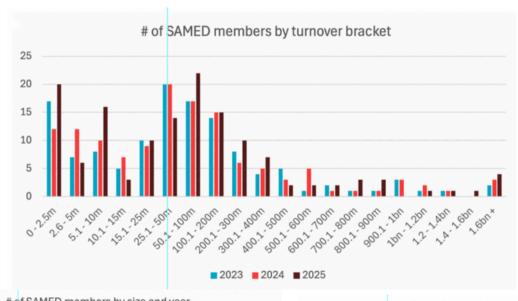
- The medtech industry has the responsibility to be inclusive – to assist health systems in all their forms and varieties to provide access to relevant and quality medtech. Inclusivity likewise entails our commitment to women and youth inclusivity and the sector's transformation, diversity and sustainability.
- The way we embrace innovation and invest in technological advancement across the entire medtech value chain needs to ensure the relevance, quality, cost-effectiveness and efficiency of products and services required by our market.

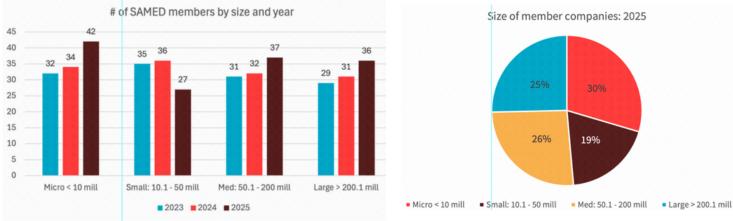


The profound and multi-faceted impact medtech has on the lives of patients, users of medtech and health systems needs to be quantified and recognised.

Between them, SAMED's 130 ordinary member companies have nearly 10 000 permanent employees and contribute many times that number in terms of training and employment opportunities generated. Together with all the products and services provided by the medtech value chain, we directly enable and strengthen the health systems we interact with.

We acknowledge and celebrate our impact, these milestones and the opportunities to support healthcare and socio-economic progress for years to come!





Dr Seoka's words are deeply resonant as we look at the evolving membership composition, illustrated in various graphs.



"SAMED is not an office.
SAMED is every
company who
is a member of SAMED."
- Dr Sybil Seoka,
SAMED board member



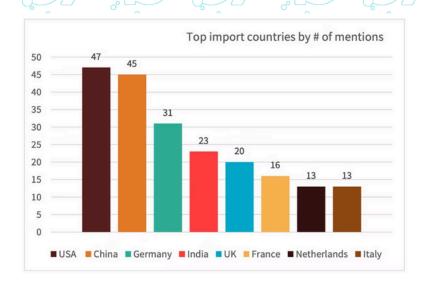
Underscoring SAMED's relevance to smaller, local companies and the growing number of small/medium-sized enterprises joining the Association demonstrates the benefits of being a member of SAMED and the valuable access this affords to business-essential information and assistance. SAMED's representation of companies of all sizes and both local and international role players shows how we can come together to jointly address the needs of the medtech sector and to serve South African patients and the healthcare system.

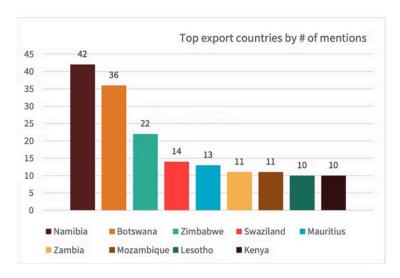
I'm delighted to include in this report graphs based on data provided recently by the members - thank you! It reveals a vibrant South African medtech sector and how it shows up internationally.

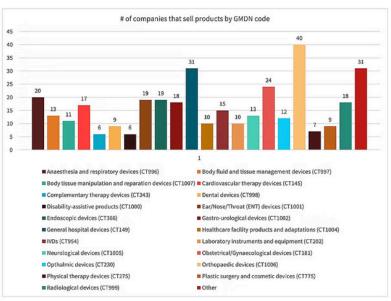
The trends still reflect the more established, pre-COVID-19 flow of health products, with South Africa importing the bulk of medtech from the larger global economies and exporting mainly into Africa.

As leaders and professionals in your various fields, I am confident you will appreciate the high value of this data. Given the various geopolitical and local dynamics, these insights assist SAMED members and medtech stakeholders to inform their shortand longer-term strategies.

Therefore, SAMED will deliberately continue to focus on research, information gathering and provision of reliable medtech sector data.









Specifically, our industry has this year faced various external matters, including regulatory complexity, economic volatility, geopolitical risks, and technological disruption. Compliance with evolving South African Health Products Regulatory Authority (SAHPRA) regulations, procurement shifts, and EU Medical Device Regulation (MDR) requirements continue to add layers of complexity to business operations. Additionally, outstanding public sector payments, exchange rate fluctuations and shifting global trade conditions present further challenges for our medtech businesses. The industry must navigate issues related to artificial intelligence, cybersecurity, digital transformation and the growing influence of non-traditional players.

During the year, three specific interconnected policies and market-related challenges emerged:

- National Health Insurance: SAMED's recently released 10-point position paper on NHI strives to simplify key factors for the transition and provide tangible, implementable, best-practice recommendations.
- MEDTECH Master Plan: SAMED is a leading, highly involved medtech stakeholder in the realisation of the Master Plan.
- Resolution of the public sector debt owed to members: Much time and effort is afforded daily to raise awareness and mobilise urgency among government role players to resolve the issue as a foundation for a better-resourced, sustainable supply of essential health technology and a functional health system going forward.

# Solving a billion-Rand government debt problem



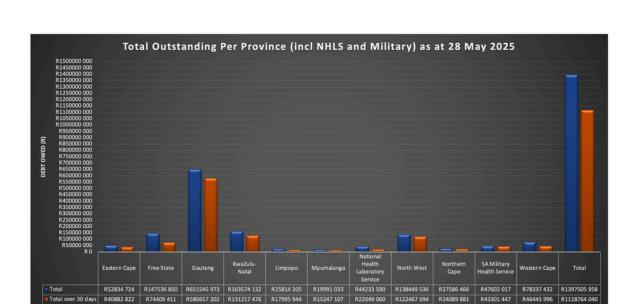
Throughout various engagements, SAMED continued to highlight primary requests and recommendations:

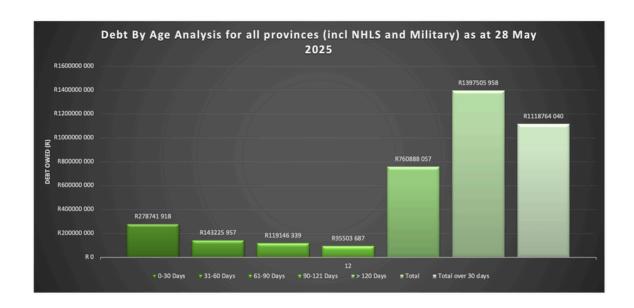
- Improving/streamlining communication between suppliers and the responsible provincial officials.
- Focusing on longstanding debt in addition to making payments for the more recent invoices.
- Strengthening provincial budgets to avoid provinces having to use next year's budget to settle current invoices.

I wish to emphasise that the best leverage we can use for these engagements is data. We need information on how much is owed to member companies so we can present accurate, current data to credibly elevate the urgency and importance of this challenge. During the year, an increasing number of member companies were submitting their information to the portal, which speaks to the relevance and seriousness of the problem.

The data from the portal is pulled and analysed quarterly, and the most recent May 2025 figures are represented here. So, if your business has government debt, please participate in the next round of data collection.







Province	Nr of companies that supplied	0-30 Days	31-60 Days	61-90 Days	90-121 Days	> 120 Days	Total	Total over 30 days
	data							
Eastern Cape	36	R11 951 902	R7 164 406	R4 687 831	R7 043 431	R21 987 154	R52 834 724	R40 882 822
Free State	33	R73 127 439	R6 928 309	RS 451 15S	R2 322 348	R59 707 599	R147 536 850	R74 409 411
Gauteng	47	R70 888 771	R74 499 347	R63 952 873	R62 479 411	R379 725 571	R651 545 973	R580 657 202
KwaZulu-Natal	39	R32 356 656	R19 392 153	R18 093 722	R8 891 545	R84 840 056	R163 574 132	R131 217 476
Limpopo	27	R7 818 261	R2 102 988	R440 867	R490 791	R14 961 298	R25 814 205	R17 995 944
Mpumalanga	22	R4 743 926	R3 239 030	R568 483	R589 290	R10 850 304	R19 991 033	R15 247 107
National Health Laboratory Service	3	R22 184 530	R1 982 212	R560 420	R783 748	R18 722 680	R44 233 590	R22 049 060
North West	38	R15 981 842	R16 195 221	R17 422 208	R9 116 861	R79 733 404	R138 449 536	R122 467 694
Northern Cape	28	R3 496 585	R2 113 625	R3 859 052	R1 462 619	R16 654 585	R27 586 466	R24 089 881
SA Military Health Service	27	R4 300 570	R719 375	R361 658	R648 548	R41 571 866	R47 602 017	R43 301 447
Western Cape	42	R31 891 436	R8 889 291	R3 748 070	R1 675 095	R32 133 540	R78 337 432	R46 445 996
Total	49	R278 741 918	R143 225 957	R119 146 339	R95 503 687	R760 888 057	R1 397 505 958	R1 118 764 040

Table: Outstanding payments to SAMED members | May 2025







### **Addressing other reimbursement matters**

During the year, SAMED initiated dialogues with the private medical scheme sector and the regulator, Council for Medical Schemes (CMS), relating to gaps in the representation of medtech expenditure and to request clearer, more transparent, accurate and medtech-appropriate data/terminology use in reimbursement processes and reports.

This data is critical! It is the basis for reimbursement guidelines, setting of fees and payment procedures.

Without insight into this information, it is difficult to correctly apportion fees and payments for medtech to suppliers against allocations for hospital or HCP fees or to challenge insufficient, misinformed or inequitable allocations for medtech products. SAMED ensured our representatives were prepared for these engagements and that we used them as strategic platforms to communicate other essential information about the industry and how to ensure medtech and innovative solutions function well across the diverse conditions under which they are applied.

I am pleased to report that we have signed a Memorandum of Understanding with CMS that will assist to realise this imperative. The MOU provides a framework for collaboration between CMS and SAMED, with a view to sharing information, data and research on medtech and supporting each other on joint projects by consulting on experiences and challenges in our respective business environments.

The partnership has facilitated SAMED's participation in CMS's policy roundtable where SAMED reiterated the message that the medtech sector lacks access to data which is vital for value-based procurement (VBP) and standardised health technology assessment (HTA) processes and requirements across multiple schemes.

SAMED held a productive engagement with Discovery Health early in the year to put forward the members' voice on cost pressures our sector faces and manages every day. In the context of value-based outcomes, the sector's contribution to essential health services and the sustainability of our industry, SAMED has requested from Discovery Health as the dominant funder to review its reimbursement models and consult with SAMED and industry when they create reimbursement models to ensure optimal health outcomes.

SAMED has also raised the matter of the high cost of commercialised published data and that it is in everyone's interest – most importantly the patients' – if those reports can be more easily accessed by the medtech industry to inform strategies.

Addressing these areas will provide insights for our sector and contribute to a more comprehensive understanding of healthcare financing in South Africa. The achievements speak directly to the SAMED strategy in multiple ways – not least of all universal healthcare access, and we undertake to keep you posted on the future benefits and outcomes of this intervention.

Another key aspect of reimbursement – and cause of the frustrations felt by some members – that SAMED addressed relates to HTAs and health economics and outcomes research (HEOR). SAMED initiated a collaboration with a service provider, Syenza, to empower members with the critical knowledge and skills needed to navigate HTAs and HEOR for market access and more effective reimbursement. The nine-month course is only accessible to SAMED ordinary members at this stage so make sure your company benefits from this offer!







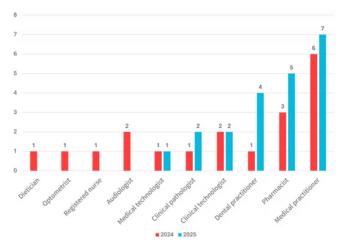


This SAMED pillar was exceptionally active during the year. I would like to recognise the Code Committee for their insights, commitment and many hours that went into revamping and upgrading the central piece in SAMED's sector self-regulatory framework – the Medical Technology Code of Ethical Marketing and Business Practice.

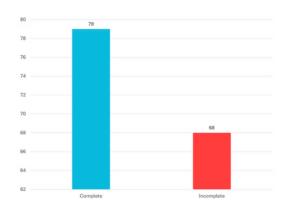
The Code is now a user-friendly digital resource that is proving to be a valuable component in the broader SAMED compliance programme. The Code is patient-centred. It promotes and encourages ethical principles and practices during medtech supplier-customer interactions. Despite its depth and breadth, the Code is nevertheless easy to navigate and contains valuable information about the activities that govern the way medtech companies do business in South Africa and their interactions with HCPs.

With leadership from SAMED's Compliance and Regulatory Manager, Alwi Spearpoint, SAMED has updated and aligned the Certification questions and criteria with the Code, as well as streamlined the certification processes and opened the Certification up to all stakeholders including healthcare professionals (HCPs) and professional conference organisers (PCOs) with the objective of deepening the Code's adoption and use.

Furthermore, becoming a signatory of the Code – as a demonstration of uBuntu and accountability – has been extended to all medtech companies, regardless of their membership of SAMED and is open to SALDA and MDMSA members as well. The intention is to raise awareness of bribery and corruption risks and to build a movement dedicated to ethics and governance throughout the industry.



Graph: The increasing Code certification by HCPs



Graph: Code certification by compliance officers of member companies





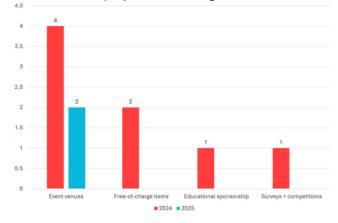
To publicise and mobilise interest and uptake of the Code and completing the Certification test among external stakeholders, SAMED published a CPD-accredited article in leading medical media and through organisations such as the Health Professions Council of South Africa (HPCSA) as part of a communication and marketing drive targeted at professional societies and conference organisers.

The graphs in this section illustrate the status of Code Certification:

- Well done to Alwi for getting the Code Certification by HCPs CPD-accredited. This will increase the
  established value of this SAMED initiative, with plans to expand accreditation to other SAMED Code
  compliance events.
- HCPs from different health disciplines are on board: 21 HCPs received certification since January and 42 have requested the Certification Voucher that allows them three free attempts (thereafter a nominal fee applies).
- The certification of member companies' staff, namely the Compliance Officers and all customerfacing employees whose certification is in progress.

SAMED diligently facilitated and monitored member company certifications, as well as managed four cases reported to the Code Hotline during the year and responded to 10 requests for advisory opinions.

As the graph on advisory opinions illustrates, the selection of compliant venues for HCP education is a complex and frequently raised topic that SAMED intends to address in collaboration with MedTech Europe and MECOMED so that SAMED gains access to the CVS platform used by these entities with the intention to simplify venue vetting for SAMED members.



Graph: Uptake of The Code advisory opiniions

Month	Code Hotline Complaint	Outcome
Aug 2024	Sponsorship of entertainment	Case closed – dismissed. No contravention of the Code
Aug 2024	Sponsorship of a congress at a	Case closed – sanctions issued
	non-compliant venue (Sun City)	
Feb 2025	Advertising of Class D medical	Case closed - referred to relevant authority (SAHPRA)
	devices on public platform	
May 2025	Sub-standard service delivery by	Case closed – outside the scope of the Code; the complainant also reported
	a laboratory	this to various other institutions including the HPCSA, Section27 and SAHPRA

Table: The Code Hotline use during the year













These initiatives are strategically connected to Project 18C that seeks Ministerial recognition of industry self-regulation codes, including the Medical Technology Code, the MCA (Marketing Code Authority) as well as the applicability of the codes to all relevant suppliers of health products. The initiative is an added element in our regulatory engagements with SAHPRA which, it is envisaged, will be a responsible party in the enforcement of these codes.

SAMED has also undertaken the following activities as part of compliance and regulatory affairs. I would like to note the stellar work by SAMED secretariat and committees which committedly apply their attention and time to source, analyse and prepare the submissions which benefit every SAMED member.

Initiative	Activities
	SAMED responded to 13 pieces of legislation during the year to strengthen regulations and help member companies prepare for compliance. While it is not always possible to influence policy once it has been passed, SAMED's ongoing member feedback assists members to formulate organisational strategies in response to the legislation.
Comment on policies and related member communication	These submissions relate to: employment equity targets; low-cost benefit options; interim block exemption for tariffs determination in the healthcare sector; traceability of health products; local manufacture and B-BBEE; health technology coding systems; clinical evaluation; investigation and post-market surveillance of medical devices; HPCSA Booklet 20 Ethical Guidelines on the use of Al; clinical investment in medtech; export of radioactive sources, draft Governance Regulations on the Establishment of the Structure of the NHI Fund and Botswana Medical Regulatory Authority's proposed regulatory fees.
	The evolving regulations are a high priority for SAMED, and the Association has collated and shared various updates with members.
SAHPRA engagements	SAHPRA is currently undertaking a feasibility study that will inform timelines and approaches to the regulations on product registration. SAMED is expecting these to be published for comment.
	SAMED appreciates SAHPRA's assistance to jointly address challenges at Port Health and consumables covered by regulations on radiation control.
Exemption of medtech from 18A and 18B	Three-year exemption extension until December 2027 has been granted.
	SAMED has continually informed members of SAHPRA communications about the timelines for the implementation of ISO13485. To enable SAMED to meaningfully represent members in SAHPRA engagements, we initiated a member survey on preparedness for accreditation which revealed various challenges that SAMED is helping to address.
ISO13485	A significant focus was placed on expanding the member companies' understanding and access to Conformity Assessment Bodies which play a crucial role in certification.
	SAMED had a fulfilling year regarding international engagements which help to lift SAMED's profile within the global medtech community and unlock exposure to information, research and best practices we can bring to South Africa. Alwi represented SAMED at two relevant events:
International affiliations and collaborations	<ul> <li>Fourth MedDevReg AfriSummit in December 2024 in Cairo, Egypt. The industry event facilitated our exposure to African regulators and networking opportunities. SAMED's attendance was acknowledged.</li> </ul>
	<ul> <li>Global Harmonisation Working Party (GHWP) Annual Meeting in December in Kuala Lumpur, Malaysia. Aimed particularly at regulators, the event focused on assessing and regulating with excellence, agility, economic stimulation, convergence and harmonisation.</li> </ul>

Table: SAMED participation in regulatory affairs during 2024-2025







### Advocacy, networking, events and public relations

The Board strategy recognises and gives prominence to these functions within the Social pillar with some of the KPIs being to: (i) establish SAMED as the go-to authority on medtech in South Africa; (ii) develop strategic lobbying and policy influence efforts; (iii) strengthen member engagement and buy-in; and (iv) improve communication with patient groups and the public.

I hope that you have noticed and have engaged with SAMED's diverse member and stakeholder communication platforms which are among key benefits to members. SAMED News and the dedicated recently introduced SAMED Compliance & Regulatory News mailers are a treasure-trove of practical, relevant, curated information. The SAMED Annual Conference and last year's AGM along with 23 other top-notch events that were attended by 3 709 delegates is worthy of celebrating!

SAMED secretariat has been recognised for our active, quality, multichannel and interesting content we prepare and distribute, for growing our LinkedIn community, for ensuring members have resources they need on the website and for advocacy, PR and networking that elevates SAMED and helps us demonstrate leadership on topics that are material to members' businesses and the medtech value chain.



To highlight just a few of the prestigious invitations and opportunities that were extended to SAMED during the year speaks to the credibility of the Association and the relevance of our work to the top-tier business, government and public sector partners and stakeholders:

- The 9th Healthcare Expo Taiwan in December 2024
- Launch of B20 in February in Cape Town and the follow-up G20 High-Level Ministerial Dialogue in April 2025 with focus on accelerating localised and regionalised manufacturing by leveraging the AfCFTA
- Shortlisting and interviewing candidates in NDOH appointment process for the Essential Equipment Specialist position





- Women Economic Assembly (WECONA) in March 2025 in Gauteng
- GMTA Board meeting and MedTech Europe Forum in May 2025
- 'Reimagining Medtech in South Africa' and scenarios for linkage-to-care workshop held at the University of Johannesburg in June 2025
- High Commission of Canada Trade Office in June 2025.

In closing, I am truly grateful to the SAMED Chairperson Scott de Oliveira for his dynamic and wise leadership and to all the Board members and Committee leadership for driving our agenda, visibility and projects, as well as engaging with stakeholders and the media during interviews on diversity, local manufacture, NHI, the outstanding public debt and ethics. These initiatives bring to life the voice of the medtech sector across public platforms and is greatly valued and appreciated.

The SAMED secretariat team – thank you for tremendous and recognised work and efforts this year! I am excited by what is ahead of us as we continue to provide value to member companies and grow the membership of SAMED and our sector.

## Tanya Vogt EXECUTIVE OFFICER





## Diversity, inclusion and localisation





In deliberately and vigorously driving transformation and diversity, SAMED has amplified the positive impact of the medtech industry beyond the straightforward contribution to healthcare and patient outcomes to address other social dynamics including youth and women empowerment.

We are immensely grateful to all the SAMED members that have supported two critical medtech industry interventions where we got to show our mettle – SAMED Women Empowerment Index (WEI) and SAMED YES 4 Youth employment programme. While these initiatives are an expression of good corporate citizenship by members, they also provide the member companies with tangible transformative business benefits.

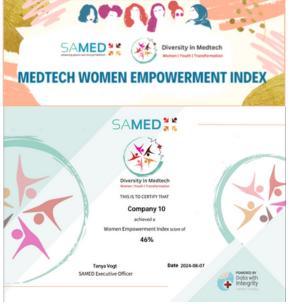
By signing up to WEI – at no cost to your company, you can obtain a certificate that benchmarks your entity's women empowerment status and progress against the industry average. This certificate can be included in business bids and tenders to improve the competitiveness of your organisation compared to suppliers that are not yet part of the initiative.

So far 29 member companies have completed their WEI data inputs on our secure Data with Integrity platform. The average member index score currently stands at 45% (see the metrics summary in the table below).

SAMED continued to promote the WEI to members as well as significant stakeholders such as SAHPRA and private hospital groups. The Executive Officer attended the 2025 Women Economic Assembly (WECONA) and presented the WEI as a blueprint that WECONA plans to introduce to other key industry sectors to enable them to follow our lead and ensure that these organisations play an active role in gender equality and transformation. WECONA was launched by President Cyril Ramaphosa with the objective to unlock partnerships to improve inclusion for women-owned-businesses in the economy and specifically supply chains.

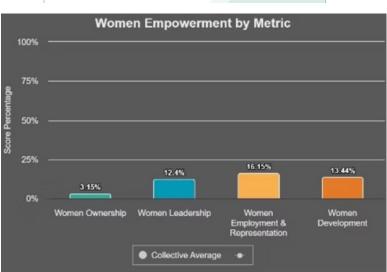
There is great synergy between WECONA and SAMED and this relationship is of strategic significance as it propels us as a thought leader in high-level business and government networks.

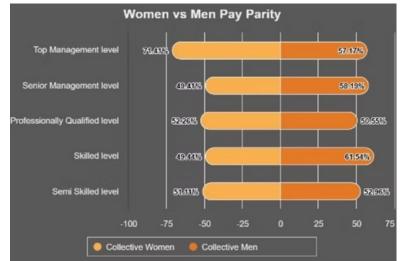
- The first published result of WEI serve as a critical baseline for members to benchmark their individual progress and for customers and other role players to track medtech industry's impact.
- The score is based on data from four key metrics. The fifth metric on Women Remuneration is voluntary and not yet included in the overall score.



Key metric	Aggregate score	Weighting	
1 Women ownership	3.2%	15%	
2 Women leadership	12.4%	30%	
3 Women employment & representation	16.2%	30%	
4 Women development	13.4%	25%	
Total	45.2%	100%	
5 Women remuneration	Measured as a ratio of the average pay of women compared to male peers employed across different levels within the business		

Table: Women Empowerment Index Score | 2025





y f in 🖸

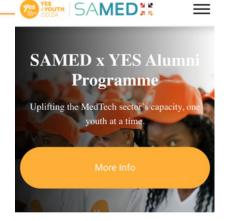
The medtech sector's partnership with YES 4 Youth has been one of our most impactful transformation achievements in the last few years. SAMED applauds the change-maker companies that have supported the initiative to date.



YES 4 Youth and 38 SAMED members have created
3 636 youth jobs (63 % female youth employees) and injected
R205 070 400 into local economies through YES Youth salaries.

More than half of the participating companies (20) have achieved a level up in their B-BBEE score by participating in the YES programme.

MEDTECH Master Plan goal is to generate 1 000 new jobs in the medtech sector over the next three years.



#### About

Welcome to the SAMED x YES Alumni Programme, a ground breaking collaboration between the South African











Whether your organisation is a medtech supplier, a hospital or another healthcare service provider, you can support YES next time you are recruiting. All you need to do is go to the SAMED X YES Alumni portal [use password samedmemberCVportal123] to access profiles for hundreds of young, trained administrators, stock controllers, marketing and other professionals.

YES 4 Youth is an invaluable resource, and we call on all SAMED members to sign up to help boost diversity, transformation, workplace energy and competitiveness across the medtech supply chain.

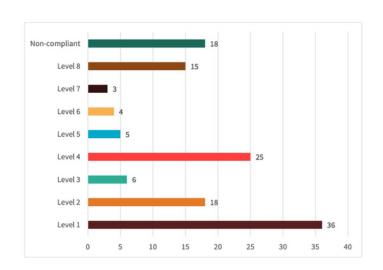
Simply put, there is enormous benefit to opening our companies and teams to young, educated and enthusiastic professionals who enrich our collectives and help us appreciate and embrace every individual's own personality and competencies.

SAMED has onboarded the second YES youth, Ntombikayise Mabuza who has already shared her talents for public relations and communication while working with SAMED's Nomthi Mnisi, Marketing, Communications and Events Manager, on SAMED's 40th anniversary branding and the upcoming annual conference.

The first YES youth, Dikapo Magolego, completed his oneyear tenure with SAMED having shown eagerness to get involved and learn, be helpful to the SAMED team and members, and taking personal pride and ownership of his work and contributions. Dikapo has recently been absorbed by Merit Medical as a Data Analyst. We wish Ntombikayise, Dikapo, and all the YES youth much success in their professional and personal endeavours!

Transformation remains a key strategic pillar for SAMED and our members. In 2024, we gathered B-BBEE data to analyse the member transformation landscape and used some of this vital information in our submissions on SAHPRA's draft B-BBEE policy and Employment Equity regulations.

The findings show encouraging progress, with many companies improving their B-BBEE levels between 2019 and 2024. However, there is still room for growth, particularly in addressing non-compliance.



Graph: SAMED member companies' latest B-BBEE scores









maisha (1) medical







































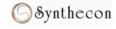


















SAMED has remained a driving force in the implementation of the MEDTECH Master Plan which was signed in May 2024. We established a Local Manufacturers Interest Group with the objective to identify synergies and activities to support the growth of the medtech manufacturing sector. The interest group is not limited to local manufacturers and welcomes engagements with all parties keen on exploring this objective, including distributors and multinationals.

SAMED coordinated the collaboration between the different industry associations with local manufacturing interests, namely MDMSA, SALDA and the Western Cape Cluster to present a unified approach by the sector towards the Master Plan. Together with these associations, SAMED has committed to a significant financial contribution to the Trade and Industrial Policy Strategies (TIPS) as the dtic-appointed provider of Master Plan Services.

The funding is specifically for the Project Manager responsible for the execution of the MEDTECH Master Plan. Vic van Vuuren was appointed as the Project Manager with effect from 1 February 2025.

Two SAMED board members, Reiner Gabler and Ian Wakefield, have been appointed to the Steering Committee for the MEDTECH Master Plan with the brief to represent the interest of SAMED member companies. SAMED also has a presence in the four sub-committees.



Pillar	SAMED representative
1   Regulatory framework	Avanthi Govender Bester and Madeleine Pearce
2   Market growth	Reiner Gabler and Ian Wakefield
3   Skills	Tracy Moonsamy and Stuart Blackbeard
4   R&D, innovation, data	Monica Lucas and Scott de Oliveira



### Financial and governance report



Thanks to the support of member companies, SAMED ended 2024 with healthy financial results. The board believes that SAMED has adequate financial resources to continue its operations for the foreseeable future and that the financial governance of SAMED is strong.

A total of 91 members (54% of SAMED membership) took the option to settle membership fees early, thereby benefitting from a 3.5% fee reduction for 2024.

The board members led by the chairperson oversaw SAMED's robust governance processes and procedures. For the first time in SAMED's 40-year history a new chairperson had to be elected during the year when the previous chairperson resigned from a member company, thereby making him ineligible to remain in the chair.

The board acknowledges Scott de Oliveira who took up the vacated chairperson role. The chair and vice chairs have provided valuable expertise and dynamic, hands-on leadership and decision-making, as well as ensured monthly engagement sessions with the SAMED Executive Officer. The board has since instituted amendments to the Association's Constitution to include roles relating to the election of chair, vice chair and treasurer and specifying the process in case of a split vote/tie in the number of votes each nominee receives.

Reiner Gabler TREASURER | SAMED board member













### **SAMED board members | 27 May 2024 - 27 May 2025**



SAMED Chairperson Merit Medical



SAMED Vice Chairperson



Reiner Gabler SAMED Treasurer **Managing Director** Gabler Medical



Anthony Lowther Resigned 28/02/2025 Smith & Nephew



Avanthi Govender Bester Associate Director: Regulatory Affairs & Quality Alcon Laboratories



Resigned 27/05/2025 Chief Executive Officer Siemens-Healthineers

Ayanda Swana

Annual Report 2024-2025

www.samed.org.za

### **SAMED board members** | 27 May 2024 - 27 May 2025



Donata Kubheka

Resigned 14/06/2024 Head: Market Access Africa Medtronic



Madeleine Pearce

Director of Regulatory Affairs: International Region, Middle East, Türkiye, Africa Philips Healthcare



Monica Lucas

General Manager Werkomed



Peter Mehlape

Resigned 27/05/2025 Independent



Stuart Blackbeard

Design Engineer Southern Implants



Dr Sybil Seoka

Managing Director
Ample Resources



Tracy Moonsamy

Group Sustainability and Risks Executive Beier





Committee	Chair	Vice chair
Code	Dr Vitor Ferrão	Sada Vlok
Diversity in Medtech	Scott de Oliveira	Tracy Moonsamy
Market Access	Keshnee Pillay	Reinhardt Zimmermann
NHI	Avanthi Govender Bester	Dr Vitor Ferrão
Regulatory	Athene Saul	Khatija Suleman



From left to right: Ntombikayise Mabuza (YES Youth Marketing, Communications, Events Intern); Linda Crystal (Executive Secretary and Membership Relations); Alwi Spearpoint (Compliance and Regulatory Manager); Tanya Vogt (Executive Officer); Ntokozo Dlamini (Projects Coordinator); Nomthi Mnisi (Marketing, Communications and Events Manager); Emily Metlhape (Office Administration Assistant)





#### **SAMED** membership

#### **ORDINARY MEMBERS**

Abbott Rapid Diagnostics (Pty) Ltd Abex Pharmaceutical (Pty) Ltd Absolute Orthopedics (Pty) Ltd Acino Forensics (Pty) Ltd

Advanced Orthopaedic Solutions (Pty) Ltd

Africoncur Medical (Pty) Ltd AHG Health Solutions (Pty) Ltd Akacia Medical (Pty) Ltd Alcon Laboratories (Pty) Ltd Allenco Medical and Dental Supplies

Alltech Healthcare (Pty) Ltd Ample Resources (Pty) Ltd Anstem Medical (Pty) Ltd

Ariste Health (Pty) Ltd

Arjohuntleigh South Africa (Pty) Ltd

Arterial Medical (Pty) Ltd Ashanti Medical cc B.Braun Medical (Pty) Ltd

Bausch + Lomb

Bcc Pharmaceuticals (Pty) Ltd Becton Dickinson (Pty) Ltd Beier Drawtex Healthcare (Pty) Ltd

BioTech Africa (Pty) Ltd

Bloemed Medical Supplies and Services cc BMG Orthopaedic Solutions (Pty) Ltd

Bone SA

Boston Scientific South Africa (Pty) Ltd

BSN Medical (Pty) Ltd
Carl Zeiss (Pty) Ltd
Casmed Logistics (Pty) Ltd
Centre for Tissue Engineering
Chairman Industries (Pty) Ltd
Cherrymed Enterprises (Pty) Ltd

Coloplast A/S

Continuous Oxygen Suppliers (Pty) Ltd Trading

as VitalAire

Convatec South Africa Corin SA (Pty) Ltd Cossni Medical (Pty) Ltd Creatori Health (Pty) Ltd Dahlhausen (Pty) Ltd

Demant South Africa (Pty) Ltd (previously Oticon)

Dimela Health (Pty) Ltd Dr Temp (Pty) Ltd

Dräger South Africa (Pty) Ltd

Duzane-Africa Medical (previously Future Med Co) Edwards Life Sciences South Africa (Pty) Ltd

Elegant Line Trading 64 cc

Elekta (Pty) Ltd Endosurgical (Pty) Ltd Ethitech (Pty) Ltd Fluorovizion Holdings Fresenius Medical Care Sou

Fresenius Medical Care South Africa (Pty) Ltd

Gabler Medical (Pty) Ltd

GE Medical Systems South Africa (Pty) Ltd

Grobir Medical Suppliers (Pty) Ltd Guerbet South Africa (Pty) Ltd H.A.S.S Southern Africa (Pty) Ltd Hartmann Vitamed (Pty) Ltd HemoCue South Africa (Pty) Ltd Hi Care Surgicial (Pty) Ltd

Imperial Market Access Healthcare SA (Pty) Ltd

Implantcast South Africa (Pty) LtdImvula Health care Logistics (Pty) Ltd

JaLo Enterprise (Pty) Ltd

Johnson & Johnson Medical (Pty) Ltd

K2 Medical (Pty) Ltd

Karl Storz Endoscopy SA (Pty) Ltd

Kiara MedTech (Pty) Ltd Langamedics (Pty) LtdLatroglo Medics (Pty) Ltd

LDK Intertrade (Pty) Ltd

Lechoba Medical Technology

Lechoba Medical Technologies (Pty) Ltd Ligamed (Pty) LtdLorumir D (Pty) Ltd Lukatit Investments 14 (Pty) Ltd ta Unitron SAMaars Medical (Pty) Ltd

Maisha Med (Pty) Ltd Maquet Southern Africa (Pty) Ltd Marcus Medical (Pty) Ltd

MED-EL Distribution (Pty) Ltd Med-EL Impant Systems South Africa (Pty) Ltd

Medhealth Supplies (Pty) Ltd
Medical International Orthopaedic cc
Medical International Trading (Pt

MedicalPerryhill International Trading (Pty) Ltd

Medical Plant Africa (Pty) Ltd

Medtronic Africa

Meducat Medical (Pty) Ltd

Melemo Medical

Mental Link International (Pty) Ltd

Merck Life Science Meril SA (Pty) Ltd

Merit Medical South Africa (Pty) Ltd

Mezotrix (Pty) Ltd Modiro Medical (Pty) Ltd Morgan Joshua Innovation Mossmed (Pty) Ltd MyOrtho Solutions (Pty) Ltd National Bioproducts Institue NPC

Neurophysics (Pty) Ltd NGL Logistics Solutions

Nipro Medical South Africa (Pty) Ltd NuAngle Solutions (Pty) Ltd

O&M Halyard South Africa Obsidian Health (Pty) Ltd OMS Medical (Pty) Ltd

Optimum Orthopaedics (Pty) Ltd

Ortho-Design (Pty) Ltd Orthomedics Ortho-Xact (Pty) Ltd Osteologix SA (Pty) Ltd





### **SAMED** membership

Paragon 28 Medical Devices Trading Limited

Patient Medical Care T/A Zebra

MedicalPerryhill International Trading (Pty) Ltd

Philips South Africa (Pty) Ltd

**Phoenix Neomed** 

Pinnacle Innovations (Pty) Ltd

Pointer Medical (Pty) Ltd

Population Services International SA (Pty) Ltd

PrimeSafe (Pty) Ltd T/A SteriTech

PrionGuard

Priontex

SAPrism Inter Africa cc

Procter & Gamble South African Trading

Professional Orthopaedics (Pty) Ltd

**Progress Medical Supplies** 

**Progressus Digital** 

Q-Surgical

Responsive Orthopaedics (Pty) Ltd

Roche Diagnostics (Pty) Ltd

SA Biomedical Holdings (Pty) Ltd

Safarmex (Pty) Ltd

Safmed (Pty) Ltd

Sea4 Medical Logistics (Pty) Ltd

Selective Surgical (Pty) Ltd

Siemens Healthcare (Pty) Ltd

Smith & Nephew (Pty) Ltd

Soflens

Southern Ear Nose and Throat (Pty) Ltd

Southern Implants (Pty) ltd

Staar Surgical (Pty) Ltd

Stiegelmeyer Africa (Pty) Ltd

Stryker South Africa (Pty) Ltd

Supra Healthcare (Pty) Ltd

Sure Medical (Pty) Ltd

Surgical and Ophthalmic Supplies (Pty) Ltd

Surgical Innovations (Pty) Ltd

SXS Surgical Solutions (Pty) Ltd

Synthecon Sutures Manufacturing SA cc

Systagenix T/A Solventum

Tara Healthcare

Teekay Link Medical Solution

Teleflex Medical (Pty) Ltd

The Scientific Group

Thogwa Medicals and Pharmaceuticals (Pty) Ltd

Umsebe Healthcare

Vertec Scientific SA (Pty) Ltd

Vertice Healthcare (Pty) Ltd

Viking BCT (Pty) Ltd

Viking Cardiovascular (Pty) Ltd

Werkomed (Pty) Ltd

WS Audiology South Africa (Pty) Ltd

Zimmer Biomed South Africa (Pty) Ltd

#### ASSOCIATE MEMBERS

AfriPharm SA (Pty) Ltd

BRANDTECH Health Technology Consulting

CEASA (The Clinical Engineering in South Africa)

**CSIR** 

**DI Medicine Regulatory Consultants** 

**Diverse Conversations** 

Dr Vitor MLdeA Ferrao Executive Consultant

DSV Solutions (Pty) Ltd

**Enterprise Ireland** 

Institute of Bio Research Auditing and Training in

Southern Africa (IBRATSA)

IQuad Integrated Management Systems (Pty) Ltd

JC Auditors

JPJ Medical

KOTRA

Mark Banfield & Associates

**Masoom Training Solutions** 

Mawele Investments cc

MC Pharma Consulting (Pty) Ltd

MEDInc SA

Regulatory For Africa

HONORARY MEMBER

Rob Millar

### ADDRESS

Hammets Crossing Office Park DOCQTECH House 816/5 2 Selbourne Road, Fourways Randburg South Africa 2191

### TELEPHONE

011 704 2440

011 704 2445

**EMAIL** 

secretariat@samed.org.za



