



**SAMED & the SA
medtech industry**

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About SAMED

Who we are

The South African Medical Technology Industry Association (SAMED) is a not-for-gain industry association. As the voice of the South African medtech and in-vitro diagnostics industry, SAMED is committed to enabling a sustainable, ethical and transformed medical technology industry that advances patient care through medtech.

In line with our Constitution we provide the medtech industry with a collective, objective and credible platform for engagement with all stakeholders.

SAMED was formed in 1985 by the following founding members: Brittan Healthcare Group; Browning Medical CC; Marcus Medical (Pty) Limited; Orthomedics (Pty) Limited; Safmed (Pty) Limited; Smith & Nephew (Pty) Limited; and Southern Implants (Pty) Limited, all of which were local manufacturers at the time. The objective of the Association then was to engage with the Regulatory Authorities and call for the registration of medical devices.

Over the years SAMED's membership has grown significantly and includes multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology') as well as the South African Laboratory and Diagnostic Association (SALDA) and the Medical Device Manufacturers Association of South Africa (MDMSA).

Medical technology plays a vital role across the continuum of patient care (prevention, screening, diagnosis, treatment and rehabilitation). As such the medical technology sector plays a significant role in providing effective and efficient health care for all South Africans.

What we do

On behalf of our members, SAMED engages with policymakers, regulators, healthcare organisations, professional societies, funders and international agencies and alliances.

We develop and support patient-centric policies that enable people to live healthy and productive lives.

We provide solutions that enhance our country's healthcare system and its productivity and accountability.

We host meetings and training workshops on matters that impact the business and sustainability of member companies.

We subscribe to the Government Gazette, Parliamentary Monitoring Group and tender bulletins. From these we collect and provide members with data that aids them in making informed business decisions.

Our organisation advocates for harmonisation of standards and regulatory requirements for the manufacture, supply and use of medical technology. To this end we are a member of two international organisations, the Asian Harmonisation Working Party and the Global Medical Technology Alliance, and work with our industry association counterparts including Mecomed in the Middle East, Medtech Europe and the USA-based Advamed

About SAMED

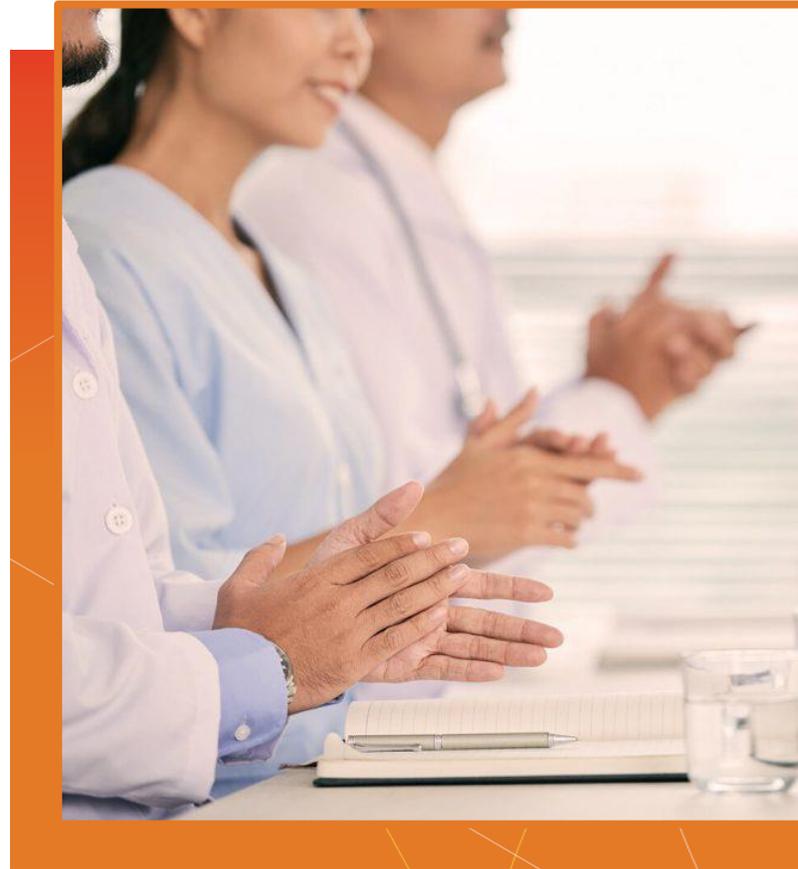
Our strategic objectives

The SAMED board sets and regularly reviews our strategic objectives in consultation with SAMED committees and members. The current SAMED strategy prioritises several areas, as explained below.

Policy, regulation and the legal frameworks

To benefit health outcomes and the national socio-economic progress, South Africa needs a well-resourced and capacitated regulatory system for the manufacture, supply, procurement and application of medical technology.

SAMED advocates for the self-regulation of the industry through the [Medical Device Code](#) on Ethical Marketing and Business Practices. The implementation of the Code is supported by an independently managed toll-free whistleblowing hotline (0800 00 04 68).



In order to strengthen the overall regulatory framework, we continually engage with the South African Health Products Regulatory Authority (SAHPRA), government including the Department of Health, Department of Trade, Industry and Competition, Department of Science and Innovation, Department of Small Business Development and National Treasury, the public and private health sector procurement and supply chain managers, healthcare providers and funders.

Growing the local medical technology manufacturing sector

We believe that South Africa's home-grown manufacture of medical technology should be actively promoted and stepped up.

A strong local medtech manufacturing sector is good for the economy. It would reduce the dependence on importing most medical technologies, mainly from the "global North". By manufacturing and buying locally, we can grow and keep expertise and skills within South Africa. A more competitive local manufacturing capacity can enhance our trade and collaborations within the African Union and strengthen local and African health systems to bring the continent closer to universal health coverage.

About SAMED

Macro-economic environment

SAMED builds on its focus on procurement and regulations as the foundation for driving legislation and practices that ensure a sustainable medtech industry. We engage on the Healthcare Masterplan, aligning with the dtic mandate and participate in the National Health Insurance and other policy discussions.

Procurement and supply chain integrity

SAMED promotes clear, transparent, practical procurement processes that recognise the complexities of the medtech industry, ensure continuity of supply, and contribute to efficiency, accountability and sustainability of the healthcare system.

SAMED supports a procurement model that appreciates the value of innovative solutions and enhances competition by various players in the industry to advance diversity across the medtech supply chain. Innovation translates into value when it prevents disease and decreases patient waiting times, length of hospital stays, morbidity and mortality.

A value-based healthcare and procurement approach:

- Helps healthcare providers and health systems plan for the short/medium/long-term implications of buying medical technology.
- Positions decisions on procurement within the context of wider patient and societal outcomes together with the life-cycle cost of healthcare delivery and services.

SAMED also undertakes capacity building initiatives both within our industry and with other stakeholders operating in procurement and supply chain management in order to improve the planning, tender specifications and procurement management and maintenance for medical technologies.



About SAMED

Our committees

The SAMED board establishes and guides the work of committees that enable us to implement the SAMED strategy and to listen to, represent and support our members. Membership of committees from across our diverse association is voluntary and encouraged. Committees' operations are supported by the SAMED Executive Officer and secretariat.

Our **Code Committee** promotes the Medical Device Code and whistleblowing hotline as the cornerstones of the medtech industry's self-regulation. It assists medical technology companies and healthcare providers in ethical marketing and business practices and interacts with third-party anti-corruption initiatives, including the Health Sector Anti-Corruption Forum which SAMED joined as a signatory in November 2019.

Our **Market Access Committee** improves collaboration with public and private healthcare facilities and funders, strengthens supply chain management and tender processes, strengthens reimbursement and HTA mechanisms in the private and public sectors and participates in Council for Medical Schemes consultations.

Our **MISA (Medical Imaging South Africa) Committee** represents the interests of companies operating in the imaging area of the medical technology industry.

Our **NHI Committee** reviews, supports and contributes to the shaping of policy, legislation and the practical implementation of the National Health Insurance.

Our **Orthopaedics Committee** represents the interests of members working in elective and trauma orthopaedics and collaborates with the South African Orthopaedic Association.

Our **SAMED / SALDA Regulatory Committee** contributes to a harmonised medical technology legislative environment, engages on policy matters with the South African Health Products Regulatory Authority (SAHPRA) and other agencies tasked with the quality, safety and effectiveness of medical technology and hosts regulatory forums to assist members with the implementation of regulations.

Our **Transformation Committee** champions the transformation of the medical technology industry and individual companies as a socio-economic imperative and key factor of the industry's sustainability.



About SAMED



Our members

SAMED membership comprises ordinary, association and associate members.

Ordinary members include multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and IVDs.

Association members are the South African Laboratory and Diagnostic Association (SALDA) and the Medical Device Manufacturers of South Africa (MDMSA).

Associate members include consultants, training providers and logistic companies operating in the medical technology industry.

As a member of SAMED, you benefit in a variety of ways:

- Be part of a broad, diverse and dynamic association that has the expertise and commitment to advocate for and protect your rights and interests.
- Engage with a community of passionate, expert industry players on common challenges and successes.
- Join SAMED committees to directly address issues that affect our industry and your organisation.
- Develop skills and stay abreast of trends, best practices and industry developments by attending regular workshops, conferences, forums and other frequent knowledge-sharing gatherings.
- Obtain guidance and support on local and international quality, licencing and regulatory requirements for medical technologies.
- Gain timely access to relevant remuneration news, benefit changes and policy trends in the market.
- Receive product and tender enquiries (local and international) and invitations to join in and outbound trade missions.

The industry we represent employs more than 4 000 people and encompasses more than 500 000 different medical devices used in the diagnosis, prevention, treatment and amelioration of disease and disability. These range from sticking plasters and wheelchairs through to pacemakers and replacement joints.

Please see the SAMED website (www.samed.org.za) for a list of our members.

The South African medtech market

Medical technology is an essential element of health provision, along with care by healthcare practitioners (HCPs) and pharmaceuticals. The term medtech encompasses technologies from the relatively simple, such as syringes and personal protective equipment (PPE), to complex and high-technology devices, including magnetic resonance imaging (MRI) machines. The medical devices industry in South Africa is diverse – it spans from local manufacturers that specialise in a limited portfolio of products to multinational distributors that cover numerous products and healthcare categories.

Size and composition of the market

South Africa is one of the largest markets in the Middle East and Africa (MEA) region. Its large population (58.8m in 2020, Stats SA) and Africa's most industrialised economy support this emerging market. According to Fitch Solutions, the medtech market is poised for considerable growth¹.

In 2019, the South African market was estimated to be worth \$1.3 billion; 3.5% higher than in 2018. The market is expected to increase further to US\$ 1.8 billion by 2023. Apart from "other medical devices", the single largest category in 2018 was consumables, making up about 19% of the total market².

| South African medical technology market by product category, 2018 | |
|---|-----------------|
| Category | USD Millions |
| Consumables | 241.00 |
| Diagnostic imaging | 199.30 |
| Orthopaedics and prosthetics | 153.70 |
| Patient aids | 156.00 |
| Dental products | 41.30 |
| Other medical devices | 487.10 |
| Total | 1 278.40 |

South Africa imports most of its medical technology/devices. The value of imports reached R15.2 billion in 2018³, compared to R2.67 billion in exports⁴.

South Africa is the primary business hub for the medical technology industry in sub-Saharan Africa. A major proportion of medical technology exports are to other countries in Africa, as shown in the table below.

The South African medtech market

Top Sub-Saharan destinations for export of medtech from SA, 2017²

| Country | USD Millions |
|------------------------------|--------------|
| Namibia | 31.46 |
| Botswana | 18.85 |
| Uganda | 9.80 |
| Swaziland | 9.69 |
| Zimbabwe | 9.55 |
| Zambia | 5.90 |
| Kenya | 5.85 |
| Mozambique | 4.82 |
| Lesotho | 3.91 |
| Malawi | 3.47 |
| Tanzania | 3.29 |
| Mauritius | 2.64 |
| Democratic Republic of Congo | 2.23 |

South Africa's spending on medical technology and devices as a proportion of wealth is on par with other MEA region markets².

The use of medical devices in South Africa can be gauged by looking at the utilisation of certain devices by medical scheme beneficiaries. By the end of 2018⁵ medical schemes had 8 916 695 beneficiaries, or about 15% of the South African population. Table below sets out the utilisation of a number of procedures using medical technologies. Most of these would have been performed in the private sector and are an underestimate of the total number of procedures performed in the country.

| Procedure (2018) | Number performed | Number per day |
|---|------------------|----------------|
| Angiogram | 23 289 | 65 |
| Bone density scan | 30 334 | 83 |
| CT (computerised tomography) scan | 457 726 | 1 254 |
| MRI (magnetic resonance imaging) scan | 274 272 | 751 |
| PET (positron emission tomography) scan | 8 087 | 22 |

The South African medtech market

Medical technology regulations, procurement and reimbursement

Due to the nature of the medical technology sector, various registration, licence and quality management regulations apply to the industry.

Legislative frameworks and agencies relevant to health regulation include the following:

National Health Act which provides a framework for a structured uniform health system, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services.

Regulations for Medical Devices and IVDs, issued under the **Medicines and Related Substances Act 1965**.

The **South African Health Products Regulatory Authority (SAHPRA)**, including the department of radiation control, has the mandate to ensure that the products under its charge are safe, effective, of good quality and in the interest of the public throughout their lifecycle. See www.sahpra.org for the current legislation, regulations and guidelines pertaining to medical devices and in-vitro diagnostics.

The **Office of Health Standards Compliance (OHSC)**, created by the National Health Amendment Act of 2013, has the mandate to protect and promote the health and safety of health services users. Its services include health inspections and the Health Ombud.

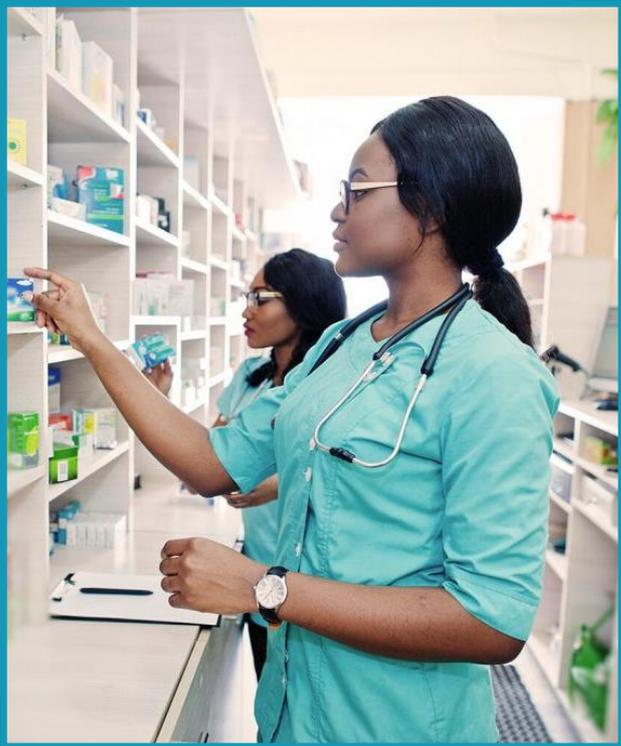
The **Council for Medical Schemes (CMS)** is a statutory body established by the Medical Schemes Act (131 of 1998) to provide regulatory supervision of private health financing through medical schemes.

Firms operating in South Africa must consider **Broad-Based Black Economic Empowerment (B-BBEE)** while conducting business. The Black Economic Empowerment (BEE) Act, No. 53 of 2003 empowers the Minister of Trade, Industry and Competition (*the dtic*) to issue Codes of Good Practice and publish Transformation Charters; establish the BEE Advisory Council; and make provision for other related matters.

Protection of Personal Information Act (POPIA) became effective on 1 July 2020. Its purpose is to protect people by protecting their personal data. The Act impacts on doctors, healthcare professionals, medical aids, insurance companies, pathologists, administrators, hospitals and organisations that need to protect employee and patient personal health data.

The **National Health Insurance** programme is in the early stages of implementation. Legislatively, the National Health Insurance Bill is under parliamentary review along with several co-dependent acts and regulations.

The South African medtech market



The government sector is the major purchaser of healthcare equipment and supplies. While a form of national tendering exists, each province has its own tendering system.

As part of initiatives to introduce national health insurance and ensure universal health coverage, the government's encouragement of public-private partnerships in the development of healthcare facilities is a new area of growth. Companies supplying primary healthcare products and services may find opportunities within the clinic building/refurbishment programmes, although for now, needs in this area are more directed towards basic infrastructure rather than clinical supplies.

Government tenders are geared towards supporting the broader socio-economic objectives. Companies wishing to operate in the public sector must demonstrate a commitment to the improvement of the health and economic status of the population in order to maintain a successful and continued presence in the market. This is linked to the Broad-based Black Economic Empowerment (B-BBEE) objectives, principles, targets and strategies. A recent focus has been the regulation that all public tender suppliers have to outsource 30% of the tender value to small and medium enterprises (SMEs) and qualifying small enterprises (QSEs).⁶

The **Preferential Procurement Policy Framework Act** (PPPFA) governs all government procurement within South Africa. The PPPFA stipulates that when government assesses contracts, it must take into account a preference point system which prescribes functionality, price and reconstruction development programme (RDP) goals.

The **Public Procurement Bill**, which when enacted into law will repeal the Preferential Procurement Policy Framework Act (PPPFA), will impact on anyone that supplies goods and services to the public sector including future NHI-related health sector procurement. The bill aims to eliminate fragmented procurement approaches and enhance the value of investment made into goods and services by government entities and programmes. The bill seeks to make public procurement more transparent and competitive and introduce measures to ensure the integrity of the procurement process. It is anticipated that this will make tendering, procurement and payment across the public sector more predictable and accountable

South African health facilities

South Africa currently has a two-tiered healthcare system, comprising the larger public (approximately 80% of the population) and the growing private sector. The country spent 9.0% of its GDP on healthcare in 2017 – higher than the 5% the World Health Organization (WHO) recommends for a country of its socio-economic status. However, despite this high expenditure, health outcomes remain poor in comparison with similar middle-income countries. This is primarily attributed to the inequities between the public and private sectors.⁷

Primary healthcare in focus

The National Department of Health views a transition from a curative model of health service to one that promotes primary healthcare delivered as close to the community as possible as one of the key strategies to strengthen the health system and improve health outcomes.

Different initiatives, fostered by the NHI programme, are directed towards achieving this, and improving access to and quality of primary and family healthcare. They include projects to strengthen existing and open new clinics and introduce and capacitate community health workers. In some areas, there is growing collaboration between the public and private health providers.

Hospital sector

South Africa has a number of public (government-managed) hospitals within its nine provinces. These are split into three categories: academic (or tertiary), district and regional hospitals. For details, see links below.

National Department of Health: <http://www.health.gov.za/>

Gauteng Department of Health: <http://www.health.gpg.gov.za/Pages/default.aspx>

Free State Department of Health: <http://www.fshealth.gov.za/portal/page/portal/fshp/intranet>

Eastern Cape Department of Health: <http://www.ecprov.gov.za/Pages/default.aspx>

KwaZulu Natal Department of Health: <http://www.kznhealth.gov.za/>

Limpopo Department of Health: <http://www.doh.limpopo.gov.za/>

Mpumalanga Department of Health: <http://www.mpuhealth.gov.za/>

North West Department of Health: <http://health.nwpg.gov.za/dohnw/>

Northern Cape Department of Health: <http://www.northern-cape.gov.za/>

Western Cape Department of Health: <https://www.westerncape.gov.za/dept/health>

In addition, a number of private hospital groups operate in South Africa. Information on some of the largest groups is available below.

Life Healthcare Hospitals: www.lifehealthcare.co.za

Mediclinic: www.mediclinic.co.za

National Hospital Network (NHN): www.nhn.co.za

Netcare Ltd: www.netcare.co.za

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¹ Figures prior to COVID-19 pandemic

² Fitch Solutions; <https://www.export.gov/article?id=South-Africa-medical-devices>; [Africa Health: Market Insights: South Africa Medical Devices Market 2019](https://www.africahalthexhibition.com/en/overview/industry-insights/healthcare-market-insights-south-africa/page-2.html)

³ SARS Trade Statistics Check

⁴ <https://www.trade.gov/knowledge-product/south-africa-medical-devices2>

⁵ Council for Medical Schemes (CMS) 2018 [Annual Report](https://www.cms.gov/annual-report)

⁶ <https://www.onlinetenders.co.za/news/30-procurement-policy-to-boost-growth-of-sme-says-zulu>, <https://www.sa-tenders.co.za/content/hints-tips-and-news/it-compulsory-sub-contract-part-tender>

⁷ <https://www.africahalthexhibition.com/en/overview/industry-insights/healthcare-market-insights-south-africa/page-2.html>



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