

PAIA MANUAL

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1. Introduction to SAMED

The South African Medical Technology Industry Association (“SAMED”), a voluntary not-for-gain industry association, is the voice of the medical technology and in vitro diagnostics (“IVD”) industry in South Africa.

2. Contact Details

Business Name:	South African Medical Technology Industry Association
Executive Officer:	Tanya Vogt
Physical Address:	Hammets Crossing Office Park, Prince House 816/4, No. 2 Selborne Road, Johannesburg North, Randburg
Postal Address:	PO Box 651761, Benmore, 2010, South Africa
Telephone Number:	+27 (0) 11 704 2440
E-mail address:	info@samed.org.za
Website address:	www.samed.org.za

3. Information Officer of SAMED

Name:	Tanya Vogt
Contact number:	+27 (0) 11 704 2440
Email address:	info@samed.co.za

4. Guide of the Information Regulator

The Information Regulator compiled a Guide, in terms of Section 10 of the Promotion of Access to Information Act (Act 2 of 2000) (“PAIA”), to assist persons wishing to exercise their rights in terms of this Act. This Guide is available in all the official languages and contains, amongst others, the following information:

- the purpose of PAIA;
- the manner, form and costs of a request for access to information held by a body;
- legal remedies when access to information is denied;

- assistance that the Information Regulator can provide;
- mechanisms to obtain the contact details of Information Officers; and
- relevant legislation.

The Guide is available in all the official languages on the website (<https://www.justice.gov.za/infoereg/>) of the Information Regulator or can be obtained from the Information Regulator at:

Physical address: JD House, 27 Stiemens Street, Braamfontein, Johannesburg, 2001

Postal address: PO Box 31533, Braamfontein, Johannesburg, 2017

E-mail address: enquiries@infoeregulator.org.za

The Guide can also be obtained upon request from the Information Officer of SAMED. A copy of the Guide is available for public inspection during normal office hours as the offices of SAMED.

5. Records

SAMED holds the following categories of records:

5.1 Association records:

Constitution; governance-related documents e.g., minutes and agendas of meetings; appointment records of board and committee members; Medical Device Code of Ethical Marketing and Business Practice (“Medical Device Code”); position statements; policies; guidelines.

5.2 Employment records:

Job application-related documents; employment contracts; conditions of employment and workplace policies; employment equity and skills development plans and reports; salary and payment records; leave records; performance management records; collective agreements; disciplinary records; training records; records related to the compensation for occupational injuries and diseases.

5.3 Client and service provider records:

Agreements; performance records; profiles; invoices, statements; payments.

5.4 Membership records:

Membership application forms and supporting documentation; Medical Device Code complaints, advisory opinions and enforcement records; invoices and statements; BBBEE¹ certificates; licences issued by the relevant regulatory authorities; surveys; turnover tiers; correspondence.

5.5 Financial records:

Annual financial statements; auditors' reports; accounting records; bank statements; invoices, statements, receipts and related documents; VAT records; tax returns and related records; asset register.

5.6 Regulatory records:

Records related to the registration of medical devices and IVDs and other relevant regulatory matters; medical device and IVD establishment licences.

5.7 Agreements:

Agreements (and related documentation) with contractors, consultants, suppliers and vendors, including rental agreements, financing and lease agreements, sale and purchase agreements.

5.8 Records relating to complaints and legal processes:

Complaint records; Medical Device Code enforcement records; pleadings, briefs and related documents pertaining to any actual, pending or threatened litigation, mediation or arbitration.

5.9 Insurance records:

Insurance policies and related records; claims records.

6. Information Available in terms of Other Legislation

SAMED holds records as may be required in terms of the legislation listed below subject to the specific protection offered by the various laws:

¹ Broad-Based Black Economic Empowerment

Applicable Legislation	Category of Records
Basic Conditions of Employment Act 75 of 1997 and Labour Relations Act 66 of 1995	Employment contracts and related documentation
Broad-Based Black Economic Empowerment Act 53 of 2003	BEE status certificates
Disaster Management Act 57 of 2002	COVID-19 screening records
Electronic Communications and Transactions Act 25 of 2002	Proof of electronic transactions
Employment Equity Act 55 of 1998	Employment equity reports
Income Tax Act 58 of 1962 and Tax Administration Act 28 of 2011	Employees' tax-related information and payments made to board members, vendors, service providers and suppliers
Occupational Health and Safety Act 85 of 1993 and Compensation for Occupational Injuries and Diseases Act 130 of 1993	Health and safety incidents; ergonomics records; claims and records related to occupational diseases and injuries
Promotion of Access to Information Act 2 of 2000	PAIA Manual and PAIA Guide
Protection of Personal Information Act 4 of 2013	PAIA Manual and policies related to the protection of personal information, including a record-keeping policy
Skills Development Levies Act 9 of 1999 and Skills Development Act 97 of 1998	Records related to payment of levies and skills development reports
Unemployment Contributions Act 4 of 2002 and Unemployment Insurance Act 63 of 2001	Records related to payment of UIF contributions and relevant employee records
Value Added Tax Act 89 of 1991	VAT records

7. Records Automatically Available

The information on the website is automatically available without having to request access by completing Form 2. Access and usage of the information on the website are subject to the Website

Terms and Conditions as well as the Privacy Policy of SAMED.

8. Purpose of Processing Personal Information

SAMED processes personal information of data subjects for the following purposes:

- to conduct the business of SAMED;
- for the administration of membership and collection of membership fees;
- for the provision of membership services;
- to communicate relevant information, industry matters and events;
- for the maintenance of its own internal and association-related records;
- for employment and related purposes;
- for appointment of board and committee members and related purposes;
- for procurement of products and services in relation to its own operations;
- for engagement with Regulators and relevant public and private bodies, local and international, on behalf of members;
- for the marketing of SAMED's services and events;
- for enforcement of the Medical Device Code;
- for Medical Device Code certification;
- for historical, statistical and research purposes; and
- for any other lawful purpose related to the business of SAMED.

9. Data Subjects, Their Information and Potential Recipients of this Information

SAMED holds the personal information in respect of the categories of data subjects specified below. The potential recipients of the personal information processed by SAMED are also specified. **Information and records are only disclosed as may be necessary in the circumstances and authorised in terms of the law or otherwise with the consent of the relevant data subjects.**

9.1 Employees

Categories of personal information:

Curriculum Vitae (CVs); names and surnames; contact details; identity numbers / dates of birth; race; gender; nationality; qualifications; registered professions; employment history and information; position held and job description; bank details; relevant health information; criminal behaviour; disciplinary-related information; correspondence; records created in the performance of their duties; tax numbers and related tax information; leave records; remuneration; employment benefits; absenteeism information; next-of-kin details.

Potential Recipients:

SAMED Board; SAMED Members; South African Revenue Services (“SARS”); relevant contractors and vendors; relevant public and private bodies; banks; vetting agencies; professional advisers (which include legal advisors); auditors; contractors and suppliers; executors of estates.

Relevant personal information of job applicants is also held by SAMED and disclosed to the SAMED Board and professional advisers, as may be relevant and required.

9.2 Board and Committee Members

Categories of personal information:

Curriculum Vitae (CVs); names and surnames; contact details; identity numbers; race; gender; nationality; qualifications; bank details; correspondence; records created in the performance of their duties; remuneration; FICA² documents where required.

Potential Recipients:

SAMED Board; SAMED Members; SARS; relevant contractors and vendors; relevant public and private bodies (e.g., the South African Health Products Regulatory Authority (“SAHPRA”); banks; vetting agencies; the public; professional advisers; auditors; contractors and suppliers; executors of estates.

Personal information of nominators and nominees as provided on nomination forms is also held by SAMED and disclosed to the SAMED Board, members, the auditors and professional advisers, as may

² Financial Intelligence Centre Act

be relevant and required.

9.3 Membership Records

Categories of personal information:

Names of members, their office-bearers and other employees; contact details; websites; BBBEE rating; race-related information; market information; medical device / IVD registration information; regulatory licences; certification; VAT information; turnover tiers; information relevant to their engagements with public bodies.

Potential Recipients:

Relevant public and private bodies; auditors; professional advisers; SAMED Board and Committees.

9.4 Contractors, Vendors and Suppliers

Categories of personal information:

Names and surnames; organisation names and details; relevant staff / office bearer details; contact details; website addresses; opinions; correspondence; market information; price structures; financial arrangements; BBBEE related information.

Potential Recipients:

Banks; auditors; professional advisers; SAMED Board and Committees.

9.5 Insurers

Categories of personal information:

Names and contact details; premiums; correspondence.

Potential Recipients:

Auditors; professional advisers; relevant public bodies; Board and Committees.

9.6 Public and private bodies (e.g., regulators and funders)

Categories of personal information:

Names; contact details; office bearers; fee / benefit structures; information produced by them; correspondence

Potential Recipients:

Professional advisers; auditors; public; SAMED Board and Committees; members.

10. Personal Information sent across the Borders of the RSA

SAMED stores electronic information, including personal information of data subjects, on servers, which may be located outside of the borders of the Republic of South Africa. Due care is taken in the selection of appropriate cloud service providers to ensure compliance with the law to protect the privacy of data subjects. SAMED is not planning to send any personal information about any data subject to any other third parties in foreign countries. Should this be required, transfers of such information will occur in accordance with the requirements of the law.

11. Security Measures to Protect Personal Information

SAMED is committed to ensuring the security of the personal information in its possession or under its control in order to protect it from unauthorised processing and access as well as loss, damage or unauthorised destruction. It continually reviews and updates its information protection measures to ensure the security, integrity and confidentiality of this information in accordance with industry best practices. The measures it adopts to ensure the security of personal information includes technical and organisational measures and internal policies to prevent unauthorised access, loss or use of personal information, for example, the physical securing of the offices where information is held; locking of cabinets with physical records; password control to access electronic records; server access control; and off-site data back-ups. In addition, only those employees, office-bearers and service providers that require access to the information to discharge their functions relating to SAMED's business will be permitted access to the relevant information and only if they have concluded agreements with or

provided undertakings to SAMED requiring them to implement appropriate security measures and to maintain the confidentiality of the information. Office-bearers and contractors / suppliers / vendors are required to adhere to the strict policies and processes implemented by SAMED and are subject to sanctions for any security breach. All security breaches are taken seriously and are addressed in accordance with the law.

12. Procedure to Obtain Access to Records or Information

The fact that information and records are held by SAMED as listed in this Manual should not be construed as conferring upon any requester any right to that information or record. Access to records and information is not automatic. PAIA grants a requester access to records of a private body, if the record is required for the exercise or protection of any right. If a public body lodges a request, the public body must be acting in the public interest.

Any person, who would like to request access to any of the above records or information, is required to complete a request form (Form 2), which is available from –

- the Information Officer of SAMED at the contact details stipulated above; and
- the Information Regulator at the contact details stipulated above.

The requester must provide sufficient detail on the request form to enable the Information Officer to identify the record and the requester. The requester must identify the right he/she/it is seeking to exercise or protect and explain why the record requested is required for the exercise or protection of that right. If a request is made on behalf of another person, the requester must submit proof of the capacity in which the request is made to the satisfaction of the Information Officer. Access to the requested records or information or parts of the records or information may be refused in terms of the law (e.g., PAIA). Requesters will be advised of the outcome of their requests.

13. Fees Payable to Obtain the Requested Records or Information

Fees may be charged for requesting and accessing information and records held by SAMED. These fees

are prescribed in terms of PAIA. Details of the fees payable may be obtained from reception or the Information Officer. The fees are also available from the Information Regulator.

14. Availability of this Manual

A copy of this Manual is available for inspection, free of charge, at SAMED's offices and on its website. A copy of the Manual may also be requested from the Information Officer against payment of fee, as may be advised.