South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR MEDICAL DEVICE CERTIFICATE OF FREE SALE

This guideline is intended to provide guidance on obtaining a Certificate of Free Sale, which serves as confirmation that the listed medical devices, including in vitro diagnostic medical devices (IVDs), are legally sold or distributed in the open market in South Africa, freely without restriction. It outlines the procedural steps to ensure consistency, transparency, and regulatory compliance in supporting the export of safe, effective, and quality-assured medical devices from South Africa. It represents the South African Health Products Regulatory Authority's current thinking on the safety, quality, and performance of medical devices and IVDs. The authority reserves the right to request additional information to establish the safety, quality, and performance of a medical device and IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used, but should be scientifically and technically justified. The Authority is committed to ensuring that all registered medical devices and IVDs will meet the requirements of the Essential Principles relating to quality, safety, and performance. Applicants must adhere to the administrative requirements to avoid delay in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the CEO and the SAHPRA website.

Document History

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DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
Authorised Representative	A natural person, resident in the Republic of South Africa, who a) has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic; b) acts on behalf of a manufacturer, importer, distributor, 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 and or certificate of registration is issued; and 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;
Certificate of Free Sale	A document issued by the South African Health Products Regulatory Authority (SAHPRA) to local manufacturers, which serves as confirmation that the listed medical devices are legally sold or distributed in the open market in South Africa, freely without restriction, in the country of origin (South Africa). A Certificate of Free Sale may be referred to as a "Certificate for Export" or "Certificate to Foreign Government" in other jurisdictions.
Classification	The medical devices regulatory framework has a classification system for medical devices and IVDs, as per regulation 11 of the Regulations Relating to Medical Devices and *In Vitro* Diagnostic Medical Devices of Act 101 of 1965 South African, and risk classification as per classification guideline SAHPGL-MD-04.
CFSF number	This is a SAHPRA-assigned 4-digit Certificate of Free Sale Folder number with CFSF as a prefix, thus having an 8-character number
FSCA	Field Safety Corrective Action is an action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device. Such actions should be notified via a field safety notice.
GMDN Code	The GMDN code refers to a code assigned within the Global Medical Device Nomenclature (GMDN) system, an internationally recognised standard for naming, classifying, and categorising medical devices.
GMDN descriptor	A standardised definition or description of a medical device term within the Global Medical Device Nomenclature (GMDN) system.
In vitro Diagnostic Medical Devices (IVDs)	Means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
License number	This is a SAHPRA-assigned 8-digit number with an MD at the end, thus having a 10-character licence number.
Manufacture	All operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling and refurbishing of a medical device or IVD, as the case may be, and includes 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
Manufacturer	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 out by that person by himself or on his or her behalf by a third party; or 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 persons 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 including IVDs	any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent- (a) used or purporting to be suitable for use or manufactured or sold for use in- (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or (ii) restoring, correcting or modifying any somatic or psychic or organic function; or (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device
CFS	Certificate of Free Sale
MD	Medical Device
POP	Proof of Payment

1. INTRODUCTION

A Certificate of Free Sale (CFS) is a certificate, issued by the South African Health Products Regulatory Authority (SAHPRA), which serves as confirmation that the listed medical devices, including IVDs, are legally sold or distributed in the open market in South Africa, freely without restriction, and approved by the regulatory authority (SAHPRA) in the country of origin (South Africa). A CFS may only be provided for medical devices, including IVDs, listed on the approved medical device establishment Licence Form: GLF-MD-06A.

The Certificate of Free Sale serves as confirmation by SAHPRA that the manufacturer is licensed and authorised by SAHPRA to manufacture the medical device/s.

NOTE:

- ***Medical devices, including IVDs have not been assessed for safety and performance by SAHPRA and are listed as part of the process to license a medical device establishment according to the activities conducted in South Africa.***

- The exemption published on the 12th of February 2025 in the Government Notice No. 5855 in Government Gazette No. 52105 is applicable.

  The exemption of manufacturers, wholesalers and distributors of class A medical and In Vitro diagnostics (only those that do not have measuring properties/ characteristics and/ or are non-sterile) from the operation of the provisions of section 22C (1) of the medicines and Related Substances Act, 1965 (Act No. 101 of 1965).

  Link:(https://www.sahpra.org.za/wp-content/uploads/2025/02/52105-12-2-Health-Separate-GG.pdf)

1.1 Purpose

This guideline outlines the process and requirements for applicants that manufacture medical devices, including IVDs, in South Africa and who wish to apply for a free sale certificate to support their export activities.

1.2 Scope

The guideline applies to;

1.2.1 A holder of a SAHPRA medical device establishment manufacturer's licence.

1.2.2 A medical device, including an IVD, may be legally manufactured in South Africa if the following requirements are met:

(a) The establishment must be the holder of a medical device manufacturer's licence issued as per section 22C of the Medicines and Related Substances Act (Act 101 of 1965) and authorised by SAHPRA to manufacture medical devices including IVDs,

(b) The medical device or IVD must be listed with SAHPRA in the medical device licence application form,

(c) The medical device or IVD must be manufactured in accordance with ISO 13485,

(d) The medical device or IVD must be intended for export to a foreign market, and

(e) The medical device or IVD is not the subject of an open recall and/ or Field Safety Corrective Action (FSCA).

1.2.3 A South African medical device establishment who is exempted as per section 36 issued in February 2025, i.e. the exemption of manufacturers, wholesalers and distributors of class A medical and *in vitro* diagnostics (only those that do not have measuring properties/ characteristics and/ or are non-sterile) from the operation of the provisions of section 22C (1) of the medicines and Related Substances Act, 1965 (Act No. 101 of 1965).

Links:

- (https://www.sahpra.org.za/wp-content/uploads/2025/02/52105-12-2-Health-Separate-GG.pdf), and
- Medicines-and-Related-Substances-Act_101-of-1965_Act_GG-40869_2017-05-26.pdf

1.3 Eligibility Criteria

To qualify for a CFS, the following conditions must be met:

(a) The product must be listed with SAHPRA in the medical device, including IVD, establishment licence application form: GLF-MD-06A.

(b) The product must be legally sold in South Africa,

(c) The applicant must hold a valid SAHPRA medical device establishment manufacturer's licence to manufacture, distribute, and export the product,

(d) The applicant must be the licence holder and or the Authorised representative as known by the Regulator, and

(e) The application refers to a:

- Class A medical device, including IVD, that has measuring properties/characteristics and/or is sterile;
- Class B medical device, including IVD;
- Class C medical device, including IVD; and
- Class D medical device, including IVD.

NOTE: The exemption of manufacturers, wholesalers and distributors of class A medical and manufacturing *in vitro* diagnostics (only those that do not have measuring properties/ characteristics and/ or are non-sterile) from the operation of the provisions of section 22C of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as published under Government Notice No. 5855 in Government Gazette No. 52105 is applicable.

2. LEGAL PROVISION

The Medicines and Related Substances Act 101 of 1965, as amended, read in conjunction with the latest published General Regulations on Medical Devices and *In Vitro* Diagnostics, provides for the regulatory oversight of Medical Devices including *In Vitro* Diagnostics (IVDs) in South Africa.

The government gazette exemption published on 12 February 2025 "The exemption of manufacturers, wholesalers and distributors of class A medical and *In Vitro* diagnostics (only those that do not have measuring properties/ characteristics and/ or are non-sterile) from the operation of the provisions of section 22C of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)" as published under Government Notice No.5855 in Government Gazette No. 52105.

3. REQUIRED DOCUMENTATION

The applicant must submit the following:

3.1 A cover letter on a company letterhead addressed to the CEO of SAHPRA with **the subject of the letter as RE: APPLICATION FOR A CERTIFICATE OF FREE SALE,** stating;

(a) The rationale for the application of a Certificate of Free Sale.

NOTE: The subject of the letterhead should state: RE: APPLICATION FOR A CERTIFICATE OF FREE SALE

(b) Product(s) for which the CFS is requested,

(c) Destination country/ ies, and the

(d) Intended use of the CFS (e.g., regulatory submission, market access).

3.2 For the applicants whom the exemption from having a medical device establishment license as per Section 22C of the Act is applicable, the following documents are mandatory to be submitted with the application form: GLF-MD-21A.

(a) A written declaration indicating that product(s) manufactured in South Africa fall within the requirements of the exemption (Government Notice No.5855 in Government Gazette No. 52105).

(b) List of products to be included in the CFS, their product risk classification as per SAHPRA Guideline No.: SAHPGL-MD-04 for-Classification-of-MD-and-IVDs and rationale for selecting the classification.

(c) Product label: Product instruction for use, marketing material and primary and secondary label.

3.3 A completed application form for Certificate of Free Sale (GLF-MD-21A) that includes at least the following information;

(a) Applicant details,

(b) Manufacturer(s) details,

(c) Product listings relevant to the specific application. The products must be included in the current SAHPRA licence application form of the manufacturer: GLF-MD-06A, for medical devices and IVDs manufactured in South Africa, as provided in sections 4.1 and 4.2 of the form respectively and exported as provided in sections 17.1 and 17.2.

NOTE: This is not applicable for establishments that intend to export only Class A non-measurable, non-sterile medical devices as per the government gazette),

(d) GMDN codes and descriptions,

(e) Product classifications. For medium to high risk (Class C) and high risk (Class D) medical devices listed in the Certificate of Free Sale application:

i. Evidence of pre-market approval/ registration/ evidence of emergency use authorisation for each listed medical device/s from at least one of the six jurisdictions recognised by SAHPRA (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualification by the World Health Organisation for IVDs;

ii. Evidence of ISO13485 certification of the original manufacturer;

iii. Declaration that the medical device/s manufactured are safe and perform as intended and that the medical device/s fulfils the Essential Principles of Safety and Performance for Medical Devices.

(f) A copy of a valid SAHPRA medical device establishment licence to manufacture medical devices.

NOTE:

- This is not applicable for an organization that is exempted - Government Notice No.5855 in Government Gazette No. 52105.
- Not applicable for establishments that intend to export only Class A non-measurable, non-sterile medical devices as per the government gazette.

(g) Bank proof of payment for the applicable fee.

4. BEFORE APPLYING FOR A CERTIFICATE OF FREE SALE

Certificates of Free Sale aim to meet the needs of the importing country. Before applying for a certificate, SAHPRA recommends that the applicant contact the relevant foreign government through their consulate to ascertain what information must be supplied to facilitate the export of the medical devices, including IVDs, to their country.

5. APPLICATION PROCESS

The completed application form (GLF-MD-21A) must be submitted electronically to the following email address: mdreg@sahpra.org.za.

5.1 SAHPRA will review the documentation to verify the validity of the medical device establishment licence.

5.2 If all requirements are met, the CFS will be issued within 15 working days.

5.3 Please ensure that on submission to the Authority, all relevant fields are completed on the form and all supporting documentation provided.

5.4 Incomplete applications will be identified as deficient, and review will not be finalised until all deficiencies are addressed.

The Authority is committed to ensuring that all medical devices, including IVDs, are of the required quality, safety, and performance. Applicants must adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

6. FORMAT OF THE CERTIFICATE OF FREE SALE

(a) The certificate will contain:

i) For applicants with a valid SAHPRA Medical Device Establishment Manufacturer License:

- Name
- Site address of manufacturer
- Licence number of the SAHPRA-licensed manufacturer of a medical device

ii) For applicants without a SAHPRA Medical Device Establishment License as per the exemption and intend to export only Class A non-measurable and non-sterile medical devices:

- Name
- Site address of manufacturer
- CFS file number i.e., CFSF [first letter of company name with unique four-digit number]

(b) Details of medical device/s intended for export and listed in this application, including:

i) GMDN code

ii) GMDN descriptor

iii) Name and/or group and/ or family of the medical device

iv) South African risk class of medical device

v) Recipient Country/ies

(c) Date of issue,

(d) Date of expiry,

(e) Name and contact details of Authorized Representative and Licence Holder,

(f) Any additional regulatory particulars required to facilitate the export of the listed medical device/s to the relevant foreign government, and

(g) Official seal (only on the original physical document collected from SAHPRA).

7. FEES

The fee for a Certificate of Free Sale is payable upon application and proof of payment, and must be submitted together with the completed application.

NOTE: Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fee schedule published in the Government Gazette.

Applicants should note that, in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), it is an offence to make false and/or misleading statements in connection with an application for a Certificate of Free Sale. A person who fails to comply with, contravenes the provisions of, or wilfully furnishes incorrect information in respect of the regulations is guilty of an offence and, upon conviction, is liable to a fine, or to imprisonment for a period not exceeding 10 years.

Payments should be made as per the latest "Guideline on the payment of fees to SAHPRA", accessible here: https://www.sahpra.org.za/document/regulations-regarding-fees-payable-in-terms-of-the-provisions-of-the-medicines-and-related-substances-act-1965-act-no-101-of-1965/

8. VALIDITY OF THE CERTIFICATE OF FREE SALE

The Certificate of Free Sale is valid for 12 months from the date of issue.

9. REFERENCES

The following related documents are referenced:

9.1 Medicines and Related Substances Act, Act 101 of 1965 as amended.

9.2 Regulations Relating to Medical Devices and *In Vitro* Diagnostic Medical Devices, Government Gazette 9 December 2016, No 40480

9.3 GLF-MD-06A: Licence Application to Manufacture Medical Devices

9.4 MD020 - Certificate of Free Sale v3 – 08092020

9.5 Regulations Regarding Fees Payable in terms of the Provisions of the Medicines and Related Substances Act

9.6 SAHPGL-MD-04: Guideline for Classification of Medical Devices and IVDs

9.7 TGA: Certificates of free sale and export certificates for medical devices Version 1.1, February 2019, https://www.tga.gov.au/sites/default/files/certificates-of-free-sale-and-export-certificates-for-medical-devices.pdf

9.8 USFDA: Exporting Medical Devices https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/exporting-medical-devices

10. VALIDITY OF GUIDELINE

This guideline is valid for a period of 5 years from the effective date. It will be reviewed on this timeframe or as and when required.