South African Health Products
Regulatory Authority
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GUIDELINE ON QUESTIONS AND ANSWERS: LICENSING OF MEDICAL DEVICE ESTABLISHMENTS

This document is intended to provide clarity on guidelines and applications for the licensing of medical device establishments.

It reflects the current situation and will be regularly updated with changes in legislation and experience gained. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available on the SAHPRA website.

Document History

Final Version	Reason for Amendment	Effective Date [21 May 2025]
1	First issue, industrial comments incorporated and published for implementation	December 2017
2	Administrative changes	November 2019
3	• Content structured on the new SAHPRA Guideline Template • Old Guideline no. 8.10 changed to a new document number SAHPGL-MD-07	February 2023
4	Update of the questionnaire and answers	May 2025

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Contents

Glossary

Abbreviation/ Term	Meaning
AMD	Amendment
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.
CC	Carbon copy
CEO	Chief Executive Officer
Classification	The medical devices regulatory framework has a classification system for medical devices and IVDs, as per the regulations of Act 101 of 1965 South African Risk Classification as per Classification Guideline (SAHPGL-MD-04).
CV	Curriculum Vitae
Distributor	Natural or legal person who a) imports or exports a medical device or IVD which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to the medical device or IVD being placed on the market under the natural or legal person's own name; and b) sells the medical device or IVD.
GMDN	Global Medical Device Nomenclature
ISO	International Organization for Standardization
IVD (*In Vitro* Diagnostic Medical Devices	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.
Manufacturer	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.
MDF NO	Medical device file number
Medical device (MD)	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.
NLIC	New licence

PPEs	Personal protective equipment
Quality Manual	A Quality Manual provides an overview of the documented quality management system which is in operation and must include information about the organisation, the facilities, the key personnel, the quality assurance policies, procedures, work instructions, controls and activities which are undertaken by the organisation to demonstrate its ability to provide medical devices and related services that consistently meet the South African regulatory requirements.
RET	Retention
RNW	Renew
SAHPRA	South African Health Products Regulatory Authority

1. INTRODUCTION

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) Amendment, No.14 of 2015, makes provision for the implementation of the regulatory oversight of medical devices in South Africa.

This document is a summary of questions that relate to the South African Health Products Regulatory Authority (SAHPRA) guidelines for licensing of medical device establishments.

Application forms:

- GLF-MD-06A: Licence Application to Manufacture Medical Devices
- GLF-MD-06B: Licence Application to Wholesale Medical Devices
- GLF-MD-06C: Licence Application to Import Distribute or Export Medical Devices

1.1 Purpose

The purpose of the document is to provide questions and answers that relate to medical device establishment licences.

1.2 Scope

The intention is to be a dynamic document that supplements the above-mentioned documents.

Refer to the SAHPRA website (www.sahpra.org.za) for further information regarding the licensing procedure.

2. LEGAL PROVISION

Medicines and Related Substances Act 1965, Act No. 101 of 1965, as amended.

3. QUESTIONS AND ANSWERS

3.1 Submission process and requirements for new and amendment applications

3.1.1 How to I access the Medical Device page on the SAHPRA website?
Visit the SAHPRA website at www.sahpra.org.za.
Click on the tab "Operational Units" at the top right of the homepage and select "Medical Devices".
The following resources will be displayed on the Medical Device homepage: • Medical Devices and *In Vitro* Diagnostics Communication to Industry • Medical Devices and *In Vitro* Diagnostics Application Forms • Medical Devices and *In Vitro* Diagnostics Guidelines • Administration (Registration of Medical Devices, fees, FAQs, processes, process flow, legislation and regulations)
3.1.2 What are the types of application forms for Medical Device Establishment Licence?
There are three different types of medical device establishment licences that applicants may apply for: • GLF-MD-06A: Licence Application to Manufacture Medical Devices • GLF-MD-06B: Licence Application to Wholesale Medical Devices • GLF-MD-06C: Licence Application to Import Distribute or Export Medical Devices
3.1.3 What type of licence can I apply for?
The type of licence to be applied for depends on the activities that being performed.
Manufacturer's Licence: • If you are carrying out activities such as packaging, labelling, servicing or refurbishment of medical devices, you will be required to apply for a Manufacturer's licence as these activities are considered as manufacturing activities. • The Manufacturing application includes manufacturing, as well as import, distribution, and export activities for medical devices/IVDs. • Manufacturers who use a third-party storage must ensure that the third-party company is a holder of medical device establishment licence.
Distributor's Licence: • If you are importing, exporting or distributing medical devices, then you will be required to apply for a Distributor's licence as these activities are considered as distributor's activities. • Distributors who use a third-party storage must ensure that the third-party company has an approved licence.
Wholesaler's Licence: • If you are procuring the medical devices from a local manufacturer or distributor and you sell them to a retailer, then you will be required to apply for a wholesaler's licence. • A wholesaler's licence does not permit you to import or export medical devices. • A wholesaler may store the products on behalf of an approved distributor or manufacturer.
3.1.4 How do I apply for a Medical Device Establishment licence?
Select "Application forms" on the Medical Device homepage (refer to 3.1.1)
Select and download the applicable licence application form (3.1.3)

Select and download the applicable licence application form:

- GLF-MD-06A: Licence Application to Manufacture Medical Devices
- GLF-MD-06B: Licence Application to Wholesale Medical Devices
- GLF-MD-06C: Licence Application to Import Distribute or Export Medical Devices

Complete the licence application form in the Microsoft Excel format.

Note: Formatting is restricted on the forms.

3.1.5 What is the difference between COVID-19 applications and Business-as-usual (BAU) applications?

COVID-19 applications are applications which have COVID-19 related medical devices (IVDs and non-IVDs), this includes rapidly developed COVID-19 test kits, rapidly developed ventilators, PPEs, face masks (surgical and respirator masks), thermometers, oximeters for example.

Business as usual applications are applications which have medical devices (IVDs and non-IVDs), and excludes the products mentioned above.

3.1.6 Which documents must be submitted when applying for a Business-as-usual medical device establishment licence?

Cover Letter:

- All applications should be submitted with a cover letter that has been prepared on a company letterhead, signed and dated by the authorised representative.
- The cover letter must be addressed to the CEO and marked for the attention of the Medical Device Unit.
- The cover letter must indicate the purpose of the submission (i.e. Application for a medical device establishment licence to manufacture, distribute or wholesale medical devices).
- The cover letter must include a list of annexures that are submitted with the application, for example:
  - Annex 1: Licence Application form
  - Annex 2: Proof of Payment
  - Annex 3: Curriculum Vitae of the Authorised Representative
  - Annex 4: Quality Manual (Manufacturers/Distributors) or Site Master File (Wholesalers)

Application forms:

- An electronic version of the completed licence application in Microsoft Excel format and PDF version initialled by the Authorised Representative on each page and signed on the declaration section.

Curriculum Vitae:

- The curriculum vitae of the Authorised Representative must be submitted.

The Quality Manual: addressing the aspects of the Quality Management System (QMS) or Site Master File (Wholesalers)

- https://www.sahpra.org.za/document/guideline-on-medical-device-quality-manual/

Proof of payment issued by the bank for the licence application fee Regulations Regarding Fees Payable in terms of the Provisions of the Medicines and Related Substances Act, 1965 (Act No. 101 Of 1965) - 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/

3.1.7 Which documents must be submitted with the application when applying for a medical device establishment licence with COVID-19 products?

Cover Letter:

- All applications should be submitted with a cover letter that has been prepared on a company letterhead, signed and dated by the authorised representative.
- The cover letter must be addressed to the CEO and marked for the attention of the Medical Device Unit.
- The cover letter must indicate the purpose of the submission (i.e. Application for a medical device establishment licence to manufacture, distribute or wholesale medical devices). The cover letter must include a list of annexures that are submitted with the application, for example:
  - Annex 1: Licence Application
  - Annex 2: Proof of Payment
  - Annex 3: Curriculum Vitae of the Authorised Representative
  - Annex 4: Quality Manual (Manufacturers/Distributors) or Site Master File (Wholesalers)
  - Annex 5: ISO 13485 certification from the original manufacturer
  - Annex 6: Evidence of premarket registration from one of the 6 jurisdictions recognised by SAHPRA
  - Annex 7: Packaging and labelling information
  - Annex 8: Instructions for use of the medical device
  - Annex 9: Technical dossier

Refer to the following documents for the communication issued by SAHPRA to industry:

- Regulatory requirements for the supply of medical devices considering the COVID-19 pandemic
- Regulatory Requirements for the manufacture, distribution or wholesale of Covid-19 serological test kits
- Regulatory Requirements for the manufacture, distribution or wholesale of Covid-19 molecular test kits

3.1.8 Who do I send the application to?

mdadmin@sahpra.org.za for BAU applications and CC mdcovid@sahpra.org.za if the application includes COVID-19 testing kits

3.1.9 How long does it take for my application to be finalised?

Timelines for applications is 6-8 weeks from the date of submission and depends on the timeous response by applicants and the submission of sufficient documents. Refer to communication to industry: Processing of licence applications

3.1.10 How do I apply to make an amendment to an approved licence?

- For all amendment applications, the licensee is required to submit the updated product listing which includes the approved products from the initial application.
- All intended updates/changes must be indicated on the cover letter (e.g. amendment of section X of the application form).
- In the case that the licensee would like to remove a product from the product list, the licensee must omit this device from the application form.

- The updated version of the application form must be used when applying for an amendment.

Download and complete the updated version of the licence application form (3.1.3) on the Medical Device homepage.

Submit the following documents to mdadmin@sahpra.org.za and cc mdcovid@sahpra.org.za if the application includes COVID-19 testing kits:

- Cover letter: Signed and dated by Authorised Representative - Attention Medical Device Unit
- Application form: Microsoft Excel format and PDF version
- Quality Manual (Manufacturers/Distributors) or Site Master File (Wholesalers)
- Proof of payment (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/)
- CV of Authorised Representative
- Proof of retention fee payments
- Copy of the licence
- Supporting documents for COVID-19 related products (if applicable)

3.1.11 What is the difference between an amendment application and a notification?

- A **notification** is when an applicant wants to make changes or update the product list on the application form with information that does not affect the details on the issued licence, such as GMDN codes, original manufacturer or supplier details, adding products of the same class that have been approved.

- A notification must still be submitted and approved; there are **currently no applicable fees.**

- A notification may be updating the product listing with medical devices/ IVDs that are the same class in which they already have approval for. However, updates that include COVID-19 products will be regarded as an amendment.

An **amendment** is where any changes that an applicant wishes to update will affect the details of the issued licence, such as:

- Change of company/establishment/entity name (where the company registration remains the same)
- Change of address/es
- Change of Authorised Representative
- Change of licence holder
- Change of Authorised Representative or licence holder contact details (telephone number, cell phone number and email address)
- Addition or removal of activities listed
- Change of QC personnel
- Change of supply chain personnel
- Addition to the product list of another class which were not approved on the issued establishment license
- Any other updates arising from incorrect information submitted to the Authority which was indicated on the issued licence

There are applicable fees for an amendment, this is subject to change as per publication in the government

gazette, refer to position statement communication to industry licence amendment.

3.1.12 How do I submit a notification?

- For a notification, the licence holder is required to submit an updated product list in the application form, the updated product list must include the products that have been approved.
- In the case that the licensee would like to remove a product from the product list, the licensee must omit this device from the application form.
- The notification will be reviewed and approved/rejected, and the licensee will be notified in writing on the outcome.

Submit the following documents to mdadmin@sahpra.org.za, the email subject of the notification must state: **Notification to update the manufacturer/distributor/wholesaler Licence [Licence no] of [Company name].**

- **Cover letter:** Signed and dated by Authorised Representative - Attention Medical Device Unit which must include a written declaration by the authorised representative indicating that the changes made to the product list (s) do not affect the class of medical device(s) which the licence holder has been approved for.
- **Application form:** Microsoft Excel format and PDF version
- **Copy of the licence**
- A written declaration by the Authorised Representative indicating that the changes made to the various section/s on the application form do not affect the details under the issued licence.
- Any other supporting documents

3.1.13 How do I request a correction to an approved licence?

An email request must be sent to mdenquiries@sahpra.org.za and indicate the information to be updated. The request will be reviewed to confirm whether the request to update licence is accepted or not and the outcome will be communicated.

3.1.14 If the Authorised Representative/ Licence Contact Holder resign from the company what will be the process to make changes?

The company must apply for a licence amendment to update details of the Authorised Representative/ Licence Holder (refer to 3.1.10).

3.1.15 Can an applicant submit a new amendment while another is in process?

No, the previous application must be finalised prior to submission of another amendment.

3.1.16 What if my application form is incomplete?

Applicants will be requested to address deficiencies during the application process. Failure to respond to deficiency letters will result in the application being rejected.

3.1.17 How do I withdraw an issued licence?

- The company must send a cover letter to request withdrawal of the said licence and the reason for withdrawal to mdadmin@sahpra.org.za and cc mdenquiries@sahpra.org.za. The cover letter should be prepared on the company letterhead, indicating the company name and licence number and should be signed and dated by the Authorised Representative.

- The **Cover letter** must be addressed to the CEO and marked for the attention of the Medical Device Unit.

- **Proof of payment** for retention fees may be requested from the company before the request is

processed.

3.1.18 Can I change from one licence type to another?

If a licence is already approved and issued to the company, and the company intends to change the licence type, they will have to submit a new application and pay the application fee. Upon approval of the licence, the company may request to withdraw the initial licence (3.1.17).

3.1.19 Why should I withdraw my distributor's licence if I am now applying for a manufacturer's licence?

The **Manufacturing** licence includes manufacturing, import, distribution, and export activities for medical devices/IVDs.

The **Distribution** licence includes import, export and distribution activities for medical devices/IVDs.

The manufacturer's licence encompasses the distributor's activities, it is not recommended for an applicant to apply for a manufacturer's licence and distributor's licence for the same site unless if the intended activities for both licences are different. The applicant will be liable to pay annual retention fees for both licences if the applicant retains both licences.

3.1.20 How do I check if my approved licence is listed on the database?

Visit the SAHPRA website: www.sahpra.org.za

Click on the tab "Databases & Registers" at the top right of the homepage and select "Medical Devices Licences Issued".

Search using the licence number indicated on the licence or covering letter or the company name
If no results are found, contact the Medical Device Unit: mdenquiries@sahpra.org.za

3.1.21 How do I confirm the classification of a device before applying for a Medical Device Establishment Licence?

Visit the SAHPRA website: www.sahpra.org.za

Click on the tab "Operational Units" at the top right of the homepage and select "Medical Devices".

Select "Guidelines"

Select and Download the Guideline for Classification of Medical Devices and IVDs

3.1.22 What is a Global Medical Device Nomenclature (GMDN) code and descriptor?

A five (5) digit numeric code and a term, name and definition used for naming, classification and categorisation of all medical devices and IVDs. Include products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

3.1.23 How do I access the GMDN code and descriptor?

Visit the GMDN Agency website: https://www.gmdnagency.org/, sign in or register to get access. Use the search function to get the correct code and term that aligns with the intended use of the product.

3.1.24 When do applications get rejected?

Applications may get rejected for the following reasons:

- If the period of review has lapsed, such as when there is no response to a query/observation within the stipulated timeframes.
- The applicant does not comply with the stipulated specifications, requirements and test reports.
- The applicant submits incorrect or falsified information.
- As per recommendation from the relevant review committees.

3.1.25 What is a section 36 application?

Refers to section 36 of Medicines and Relates Substances Act 101 of 1965, that allows companies to apply for exemptions to the operation of any or all provisions of this Act, under specific conditions or circumstances.

- Medicines and Related Substances Act 1965, Act No. 101 of 1965, as amended

3.1.26 Who should I contact if I have more questions or require more information?

Applicants must send an email to mdenquiries@sahpra.org.za or enquiries@sahpra.org.za or call the SAHPRA reception landline on **(012) 501 0300** or use the SAHPRA Help Desk - https://www.sahpra.org.za/general-enquiries-2/

3.1.27 What is a certificate of free sale?

A Certificate of Free Sale is a certificate, which serves as confirmation that the listed medical devices 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 Certificate of Free Sale may be referred to as a "Certificate for Export" or "Certificate to Foreign Government" in other jurisdictions.

The Certificate of Free Sale serves as confirmation by SAHPRA that the manufacturer is licensed by SAHPRA to manufacture medical devices/IVDs and is the original manufacturer of the listed products.
Note: The medical device/s has/have not been assessed for safety and performance by SAHPRA.

The Certificate of Free Sale will be valid for a maximum period of one year in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

3.1.28 How do I apply for a certificate of free sale?

Select "Communication to Industry" on the Medical Device homepage.

Select and download the application form a Certificate of Free Sale for Medical Devices and IVDs

Complete the form and submit the following documents to mdadmin@sahpra.org.za:

- Cover letter on a company letterhead indicating intention to apply for a Certificate of Free Sale.

NOTE: the subject of the letterhead should state: **RE: Application for a Certificate of Free Sale**

- The completed Certificate of Free Sale Application Form
- A copy of a valid SAHPRA medical device establishment licence to manufacture medical devices
- Product listings, included in the current SAHPRA licence application of the manufacturer, for medical devices and IVDs manufactured in South Africa, as provided in section 4.1 and 4.2 respectively and exported as provided in section 17.1 and 17.2
- Proof of payment for R1 460 (https://www.sahpra.org.za/fees-2/)
- **For medium to high risk (Class C) and high risk (Class D) medical devices listed in the Certificate of Free Sale application:**
    - 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, Health Canada, Europe, Japan, USFDA) or pre-qualification by the World Health
    - Evidence of ISO13485 certification of the original manufacturer
    - Declaration that 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

The Certificate of Free Sale application process will be finalised within fifteen (15) days from the date of submission, provided that the application submitted is complete and meets the requirements.

3.1.29 If responses are not received on communications sent from industry to SAHPRA, what is the

escalation process? What timeframe should industry reasonably apply?
Escalate to the key contacts which are included on the website.

3.2 Submission process and requirements for renewal applications

3.2.1. When do I need to submit my license to the Authority for renewal?
The license renewal application must be submitted at least 90 days prior to the license expiry date. The current licence can be used to confirm the organisation's license expiry date.
3.2.2. How do I apply for a Medical Device Establishment license renewal?
Download and complete the recent version of the licence application form (3.1.3) on the Medical Device homepage (if applicable).

Submit the following documents to mdadmin@sahpra.org.za or mdcovid@sahpra.org.za, email subject: Establishment License Renewal- Licence number_Company name
 	
• Application form: Microsoft Excel format and PDF version
• Cover letter: Signed and dated by Authorised Representative - Attention Medical device Unit
  o The intention of the application on the subject matter
  o List non-exhaustive
  o Addition and or subtraction of product listing in relevant tables as per organisation's activities
  o Mention any update made that may affect the information details of the current license (If any)
  o List of attachments
• Quality Manual (Manufacturers/Distributors) or Site Master File (Wholesalers)
• Proof of payment (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/) - The fee for a medical device establishment licence application renewal is payable upon submission.
• CV of Authorised Representative
• Proof of retention fee payments
• Copy of the licence
• Supporting documents (if any)
• A certified copy of the ISO 13485:2016 – if the organisation is accredited

3.2.3. How long does it take to process the application?
The processing of the establishment license renewal application by the Authority may be for a period of at least 6 to 8 weeks. **Note:** The applicant must ensure that all documents are submitted to minimise the unforeseeable delays on the review of the application; the applicant is required to respond to the deficiencies noted in the observation letter within 2 working days of receiving the communication letter.
Only 2 review opportunities are allowed.
3.2.4. Can I include amendments to my Establishment License renewal application?
Changes that are regarded as a notification are permitted during a renewal application. **Changes that are regarded as an amendment are not permitted during a renewal application, such changes include:** • Change of company/establishment/entity name • Change of address/es • Change of authorised representative • Change of licence holder

- Change of authorised representative or licence holder contact details (telephone number, cell phone number and email address)
- Update to company's activities
- Change of QC personnel
- Change of supply chain personnel
- Addition to the product list of another class of product which were not part of the latest issued establishment license

Note: The amendment can only be done only once the renewal establishment application is completed. That is, the applicant has been issued their latest Establishment license so to ensure that the license does not expire while awaiting finalisation of the amendment process .

3.2.5. What if I submit a renewal application in less than 90 days of expiry?

Renewal applications submitted less than 6 weeks prior to expiry will not be accepted. Applicants are required to submit a new licence application as the licence will expire while the application is being processed.

3.2.6. What if I submit a renewal application after the licence is expired?

Submissions of applications which have superseded the licence expiry date will not be accepted; applicants will be required to submit a new licence application as the licence has superseded the expiry date.

In terms of section 22C(6) of the Medicines and Related Substance Act, no medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, Scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.

3.3 Cost related to a medical device establishment licence

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 fees' structures, as published in the Government Gazette.*

3.3.1. How much does it cost to apply for a Medical Device Establishment Licence?

The fees payable are determined in consultation with National Treasury and are published in the *Government Gazette*.
Regulations Regarding Fees Payable In Terms Of The Provisions Of The Medicines And Related Substances Act, 1965 (Act No. 101 Of 1965)

The following fees, are currently applicable for new applications, renewals, and amendment:

a) New Applications
   - Manufacturer's Licence Application Fee – R26 200
   - Distributor's Licence Application Fee – R15 600
   - Wholesaler's Licence Application Fee – R15 600

b) Amendment application – R5 500

c) Licence issuing (referred as collection fee) – R3 500

d) Renewal application
   - Manufacturer's Licence Renewal Fee – R22 900
   - Distributor's Licence Renewal Fee – R13 100
   - Wholesaler's Licence Renewal Fee – R13 100

e) Annual retention– R4 400

f) Notification – R0 (no fees applicable) g) Certificate of free sale – R1 460
The application fee for applications is payable before submission of the application and proof of payment should be submitted.
The licence issuing fee (also referred as Collection fees) for a medical device establishment licence application is payable when the notice of approval is sent to the applicant, and a proof of payment should be submitted before the licence is issued.
3.3.2. What is an annual retention fee?
Annual retention fees are applicable to existing licence holders in order to retain their licence, licence holders that wish to withdraw their licence can refer to 3.1.17.
Annual retention fee come into effect the year after the licence is approved by the Authority on or before the last working day of June that year, failing which the licence may be cancelled.
3.3.3. How do I make a payment to SAHPRA?
Payments to the SAHPRA must be made through electronic funds transfer (EFT).
The SAHPRA banking details are: **Bank: ABSA Bank** **Account name: South African Health Products Regulatory Authority** **Account type: Cheque Account** **Account number: 40 5939 2080** **Bank branch code: 632005**
Swift Code/ Reference Number for application fee for a new licence application: **MD NLIC *company name***
Swift Code/ Reference Number for application fee for a renewal licence application: **MD RNW *company name***
Swift Code/ Reference Number for application fee for an amendment application: **MD AMD * company name***
Swift code/ Reference Number for licence issuing fee: **MDF NO *company name***
Swift code/Reference Number for retention fee: **MD RET *company name***
Refer to SAHPRA payment guideline for payment references on the website
3.3.4. What is the process if an applicant wants to apply for a refund for overpayment?
The applicant must apply for a refund from the finance department using the SAHPRA payment guideline for guidance.
3.3.5. What is the process if the applicant submitted an application without payment or with insufficient payment?
The applicant will be informed via email to provide the proof of payment for the application fee or a top-up; the application will not be processed if the proof of payment is not provided.

3.4 Quality Manual and site master file

3.4.1. Who needs to submit a Quality Manual?
Manufacturers and Distributors of medical devices and IVDs. A guideline on Guideline on Medical Device Quality Manual is available on the SAHPRA website.
3.4.2. Who needs to submit a Site Master File?
Wholesalers of medical devices and IVDs
3.4.3. What is ISO 13485?
A certificate issued by the International Organisation for Standardization (ISO) to a company that complies with the requirements for regulatory purposes for a medical devices Quality Management Systems (QMS).

3.4.4. Who needs to submit ISO 13485 accreditation certificate and when will it be compulsory?
The ISO 13485 needs to be submitted by manufacturers and distributors, and it will be compulsory upon communication from SAHPRA. The list of conformity assessment bodies (CABs) is available on the SAHPRA website.
3.4.5. ISO 13485 accreditation will be a licence requirement at the end of the exemption period, the cost is significant due to lack of CABs. Will start-up/micro enterprises be expected to be ISO certified before they can get an establishment licence to start trading?
The requirement will be mandatory to manufacturers and distributors of medical devices and IVDs.

3.5 Relationship between SAHPRA and other regulatory bodies and partners

3.5.1. What is the role of Port Health?
To prevent, protect and provide public health response by monitoring the Points of Entry against the health risks associated with cross-border movement of people, conveyances and imported cargo.
3.5.2. Where must I go if my products are being held at Port Health and are categorised as medical devices?
For any queries related to port health shipment, contact the MD unit mdenquiries@sahpra.org.za and regulatory compliance unit under key contacts.
3.5.3. What is the role of the Medical Device Unit in relation to Port Health?
Upon referral for consignments, the MD unit reviews the documentation provided and furnish the port health technicians with a recommendation on the consignment.

3.6 Other questions

3.7.1. Can someone be an Authorised Representative to more than one company?
Yes, it is only acceptable in two scenarios, one for an authorised representative that acts on behalf of the companies within the same address/province and for companies where the Regulatory oversight is at the head office.
3.7.2. Can one company apply for different type of licenses on the same premises?
Yes, a company can hold more than one licence based on the activities being performed at the site, payment of retention fees will be applicable for each licence.
3.7.3. Can an applicant make any changes to an application that has already been approved?
No, any changes made after the application is finalised will be considered amendments and the applicant will have to follow the licence amendment application process.
3.7.4. What happens if one of the shareholders leaves the company?
The amendment process must be followed if the shareholder is the authorised representative, licence holder, supply chain or QC personnel.

4. REFERENCES

The following related documents are referenced:

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

4.2 GLF-MD-06B: Licence Application to Wholesale Medical Devices

4.3 GLF-MD-06C: Licence Application to Import Distribute or Export Medical Devices

4.4 Guideline On Medical Device Quality Manual

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

4.6 Regulatory requirements for the supply of medical devices considering the COVID-19 pandemic

4.7 Regulatory Requirements for the manufacture, distribution or wholesale of Covid-19 serological test kits

4.8 Regulatory Requirements for the manufacture, distribution or wholesale of Covid-19 molecular test kits

4.9 Processing of licence applications

4.10 Communication To Industry Licence Amendment

4.11 Guideline for Classification of Medical Devices and IVDs

4.12 Certificate of Free Sale for Medical Devices and IVDs

5. VALIDITY

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