



## SOUTH AFRICA UPDATE

# Guideline on Questions and Answers: Licensing of Medical Device Establishments

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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 from the office of the CEO and the website.

### Document History

Final Version	Reason for Amendment	Effective Date
1	First issue, industrial comments incorporated and published for implementation	December 2017
2	Administrative changes	November 2019
3	<ul style="list-style-type: none"> <li>- Content structured on the new SAHPRA Guideline Template</li> <li>- Old Guideline no. 8.10 changed to a new document number SAHPGL-MD-07</li> </ul>	February 2023

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## Glossary

Abbreviation/ Term	Meaning
Authorized Representative	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 License, distributor License, wholesaler License 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;
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 8.05.
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.
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.
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
Medical device	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
Quality Manual	A Quality Manual provides an overview of the documented quality management system which is in operation and must include information about the organization, the facilities, the key personnel, the quality assurance policies, procedures, work instructions, controls and activities which are undertaken by the organization to demonstrate its ability to provide medical devices and related services that consistently meet the South African

	regulatory requirements.
Wholesaler	A dealer who purchases medical devices or IVDs from a manufacturer or distributor and sells them to a retailer.

## 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 licence of medical device establishments:

- a) SAHPGL-MD-06 Guideline for a licence to manufacture, import, export or distribute medical devices and IVDs
- b) 16.04 Licence to act as a wholesaler of medical devices and IVDs
- c) Position paper for Amendments
- d) SAHPGL-MD-04: Classification guideline
- e) SAHPGL-MD-05: Medical device Quality Manual

Application forms:

- a) 6.21 Licence Application to manufacture, import, distribute or export medical devices
- b) 6.22 Licence Application to import, distribute or export medical devices
- c) 6.26 Licence Application to Wholesale Medical Device

And represents the South African Health Products Regulatory Authority current view.

### 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 and the above-mentioned documents.

Refer to the SAHPRA website ([www.sahpra.org.za](http://www.sahpra.org.za)) for further information regarding the licensing procedure.

## 2. LEGAL PROVISION

2.1 Section 22C of the medicines and related substance Act 101 Of 1965

### 3. QUESTIONS ABOUT SUBMISSION REQUIREMENTS

#### 3.1 How to submit a medical device establishment license application?

<b>3.1.1 What are the types of applications for Medical Device Establishment License?</b>
<p>There are three different types of medical device establishment licences that applicants may apply for:</p> <ul style="list-style-type: none"> <li>a) Manufacturer license</li> <li>b) Distributor license</li> <li>c) Wholesaler license</li> </ul>
<b>3.1.2 What type of license can I apply for?</b>
<p>The type of licence to be applied for depends on the activities that you are performing.</p>
<p>If you are doing any 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 activities, as well as import, distribution, export activities for medical devices/IVD's.</p> <p>Manufacturers who use a third-party storage must ensure that the third-party company has an approved license.</p>
<p>If you are importing, exporting or distributing medical devices then you will be required to apply for a Distributor’s license as these activities are considered as distributor’s activities.</p> <p>Distributors who use a third-party storage must ensure that the third-party company has an approved license</p>
<p>If you are procuring the medical devices from a local manufacturer or and you sell them to a retailer or distributor then you will be required to apply for a wholesaler’s license.</p> <p>A wholesaler’s license does not permit you to import or export medical devices.</p> <p>A wholesaler may store the products for an approved distributor or manufacturer.</p>
<b>3.1.3 What is the difference between COVID-19 applications and Business-as-usual applications?</b>
<p>COVID-19 applications are applications which have COVID-19 related medical devices (IVD’s and Non-IVD’s), this includes rapidly developed COVID-19 test kits, rapidly developed ventilators, PPEs, face masks (surgical and respirator masks), thermometers, oximeters for example.</p>

Business as usual applications are applications which have medical devices (IVD's and Non-IVD's), and excludes the products mentioned above.

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

All applications should be submitted with a Cover letter that has been prepared on a company letterhead, signed by the authorised representative and it should be dated.

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 and Signed by the authorised representative, for example: 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)

An electronic version of the completed licence application in MS Excel format (manufacturer or distributor application) or MS Word format (wholesaler application).

The curriculum vitae of the Authorised Representative and the Quality Manual (for Manufacturers and Distributors) or the Site Master File (for Wholesalers) must also be submitted.

You are required to submit a PDF version of the licence application, initialled by the Authorised Representative on each page, along with the proof of payment of the licence application fee.

#### 3.1.5 How do I apply for a Medical Device Establishment license?

Visit the South African Health Products Regulatory Authority (SAHPRA) website at [www.SAHPRA.org.za](http://www.SAHPRA.org.za).



Click on the tab “Health products” at the top of the page.
Click on the tab “Medical devices”, which is the fourth tab under the health products tab on the SAHPRA’s home page.
Select “Application Forms”, which is the first link on the medical devices tab..
Select and download either licence application form: <ul style="list-style-type: none"> <li>a) 6.21 – Manufacturer’s Licence;</li> <li>b) 6.22 – Distributor’s Licence;</li> <li>c) 6.23 – Wholesaler’s Licence</li> </ul>
Complete the relevant application form (in MS Excel format / MS Word) and submit with the relevant supporting documents ( <b>refer to subsection 5 for the supporting documents</b> ) and send to the following email address for business-as-usual applications: <a href="mailto:mdadmin@sahpra.org.za">mdadmin@sahpra.org.za</a> , or submit to the following email address for COVID-19 related applications: <a href="mailto:mdcovid@sahpra.org.za">mdcovid@sahpra.org.za</a> .  <b>Also refer to Annexure A below, for a step-by-step guideline.</b>
<b>3.1.6 How do I apply for an amendment to an approved license?</b>
Visit South African Health Products Regulatory Authority (SAHPRA) website at <a href="http://www.SAHPRA.org.za">www.SAHPRA.org.za</a> .
Click on the “health products tab” on the top of the page.
Click on the “medical devices tab”, which is the fourth tab under the health products tab on SAHPRA’s home page.
Select “Application forms”, which is the first link within the medical devices tab
Select and download either license application form: <ul style="list-style-type: none"> <li>a) 6.21 - Manufacturer’s license</li> <li>b) 6.22 - Distributor’s license</li> <li>c) 6.23 - Wholesaler’s license</li> </ul>
Complete the relevant application form ( in MS Excel format / Ms Word) and submit the application form and supporting documents ( <b>refer to subsection 3.1.4 for the supporting documents</b> ) and send to the

following email address for business-as-usual applications: [mdadmin@sahpra.org.za](mailto:mdadmin@sahpra.org.za), or submit to the following email address for COVID-19 related applications: [mdcovid@sahpra.org.za](mailto:mdcovid@sahpra.org.za).

**Also refer to Annexure A below, for a step-by-step guideline**

For all amendment applications, the licensee is required to submit the updated product listing which includes the already approved products and indicate the changes made on the cover letter.

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.

Once the amendment is approved, the license will reflect the updated product list as submitted by the licensee.

### 3.1.7 What is a notification?

Any change that a license holder makes that does not affect the details or listed on the license and does not change the class of medical device / IVD of which the applicant has been approved and licensed for.

The license holder is required to notify the authority (SAHPRA) of these changes by submitting a notification, which details these changes.

### 3.1.8 How do I submit a notification?

The notification cover letter must be prepared on the Company letterhead of the license holder.

The subject of the notification must state: **Notification of amendment to section(s) [x] of the manufacturer/distributor/wholesaler Medical Device Establishment License [ License no] of [Company name] [MDF Number].**

For a notification, the license holder is required to submit an updated product list in the application form (this updated product list includes the products that have been approved).

In the case that the license holder wants to remove certain medical devices from their product list then the updated product list should omit these items.

The notification will be approved according to the latest updated product list submitted by the license holder.

A written declaration by the authorised representative indicating the changes made to the product list (s) that does not affect the class of medical device(s) which the license holder has been licensed for.

The notification must be dated and signed by the authorised representative.

The notification must be accompanied by a fully completed medical device establishment license

application form, which will include the updated product list as indicated in the written notification.

An electronic version (PDF version) of the completed licence application that is initialled on each page by the authorised representative as well as an MS Excel format/ MS Word format of the application form.

All documents are to be submitted to the following email address: [mdnotifications@sahra.org.za](mailto:mdnotifications@sahra.org.za)

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

- A notification is when an applicant wants to make changes to their company previous application that does not affect their previous license issued.
- A notification must still be reported and approved, there are **currently no applicable fees** in Medical Devices.
- **A notification may be updating the product listing with medical devices/ IVD's that are the same class in which they already have approval for.** However, there are exceptions- all **updates that include Covid-19 products will be regarded as an amendment.**

An amendment is where any changes that an applicant makes will affect the details or listed on the license they were issued.

- E.g. Change of address, change in authorized representative, change of contact details or the authorized representative or license holder, change of company name, change of license holder, change in the activities listed on the current license.
- There are applicable fees for an amendment, which currently costs R5 300, this is subject to change as per publication in the government gazette.
- Refer to position statement [communication to industry license amendment](#), For Notifications and amendments:

[https://www.sahpra.org.za/wp-content/uploads/2020/01/Communication-to-industry\\_licence\\_amendment\\_nov2019.pdf](https://www.sahpra.org.za/wp-content/uploads/2020/01/Communication-to-industry_licence_amendment_nov2019.pdf)

### 3.1.10 If the Authorized Representative/ License Contact Holder resign from the company what will be the process to make changes?

The company must apply for an amendment to their license. This means the company must follow the amendment application process.

Refer to section 3.1.4 for the amendment process and requirements.

Refer to position statement [communication to industry license amendment](#),

For Notifications and amendments:

[https://www.sahpra.org.za/wp-content/uploads/2020/01/Communication-to-industry\\_licence\\_amendment\\_nov2019.pdf](https://www.sahpra.org.za/wp-content/uploads/2020/01/Communication-to-industry_licence_amendment_nov2019.pdf)

### 3.1.11 Can applicant submit new amendment while other is in process?

No, the previous application must be concluded prior to submission of an amendment.

### 3.1.12 What if my Medical Device Establishment License is incomplete?

There are 2 different screening processes that take place for a medical device establishment license application- that is the administrative and technical screening.

Applicants may be asked to address deficiencies after administrative screening and or technical screening.

During process of admin screening the medical device license application, the screener will contact the applicant by email if it is determined that any information necessary for the license application is missing.

The applicant will be provided with observation letter stating deficiencies.

Failure to respond to a deficiency notice will result in the rejection of the application.

Where the expedited regulatory pathway is applied, applicants are given 2 working days to respond to technical observation letters, however for business as usual applications, applicants are given 10 working days to respond to the observation letter issued.

During the process of technical screening, the technical evaluator will contact the applicant by email if it is determined that any information is missing. The applicant will be provided with the observation letter stating the deficiencies. Failure to respond to a deficiency notice will result in the rejection of the application. Where the expedited regulatory pathway is applied, applicants are given 2 working days to respond to technical observation letters, however for business as usual applications, applicants are given 10 working days to respond to the observation letter issued.

For expedited COVID applications the review period is 10-15 working days, depending on the completeness of the application and the timeous response by the applicants to the observation letters issued to the applicant.

For business-as-usual applications the review period is 6-8 weeks, depending on the completeness of the application and the timeous response by the applicants to the observation letters issued to the applicant.

Refer to communication to industry:

[Processing of Medical Device Establishment License Applications made to SAHPRA](#)

[MD019-Processing-of-licence-applications-v1-22072020.pdf \(sahpra.org.za\)](#)

### 3.1.13 How long does it take to get a license for a Medical Device Establishment?

Each license application is evaluated and pronounced upon by the Medical Device Peer Review Meeting. The timelines for licensing are thus dependent on the date of the submission of the application by the applicant and the meeting dates of the Medical Device Expert Committee (for Covid-19 test kit applications) and the Medical Device Peer Review Meetings. Timelines for applications also depends on the timeous response by applicants and the submission of complete applications.

The average time for an applicant to be issued with a license is 10-15 working days for complete COVID applications and 6-8 weeks for complete business as usual applications.

Refer to communication to industry:

[Processing of Medical Device Establishment License Applications made to SAHPRA](#) [MD019-Processing-of-licence-applications-v1-22072020.pdf \(sahpra.org.za\)](#)

### 3.1.14 Can I amend from Distributor to Manufacturer/ Wholesaler to Distributor?

If a company is already licensed as distributor and intends to change to Manufacturer/ Wholesaler and vice versa. They will have to submit a new application and pay the full fee for the relevant application.

### 3.1.15 Why should I withdraw my distributor's license if I am now applying for a manufacturer's license?

- The Manufacturing application includes manufacturing activities, as well as import, distribution, export activities for medical devices/IVD's.
- The Distribution application is for import, export and distribution activities for Medical Devices/IVD's only.
- The manufacturer's license encompasses the distributor's activities therefore if an applicant is applying for a manufacturer's license for the same site as the distributor's license site, it is advisable to withdraw the distributor's license.
- Should the applicant retain the distributor's license then the applicant will then have to pay retention fees for both licenses, when the retention fees are due.

### 3.1.16 How should I confirm the classification of a device before applying for a Medical Device Establishment License?

Visit the South African Health Products Regulatory Authority (SAHPRA) website at [www.SAHPRA.org.za](http://www.SAHPRA.org.za).

Click on the tab “Health products” at the top of the page.

Click on the tab “Medical devices”, which is the fourth tab under the health products tab on the SAHPRA’s home page.

Select “Guidelines”, which is the third link on the medical devices tab.

Download the guideline titled: Classification of medical devices and IVDs (refer to Annexure B below for a step-by-step guideline on how to download guidelines).

### 3.1.17 When do applications get rejected?

Applications may get rejected for the following reasons:

- a) the period of review has lapsed, such as when there is no response to a query/ observation within the stipulated timeframe.
- b) The applicant does not comply with the stipulated specifications, requirements and test reports.
- c) The applicant submits insufficient information.
- d) The applicant submits incorrect or falsified information.
- e) As per recommendation from the NHLS, Medical Device Committee, COVID Expert Committee as well as the Ventilator Expert Committee.

### 3.1.18 Which documents must be submitted when applying for a medical device establishment licence with COVID-19 products (this includes mask, respirator’s, thermometers and oximeters)?

All applications should be submitted with a Cover letter that has been prepared on a company letterhead, signed by the authorised representative and it should be dated.

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 and Signed by the authorised representative, for example: Application for a medical device establishment licence to manufacture, distribute or wholesale medical devices.

The Cover letter must include a list of the attachments 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: SANS certificate or NRCS certificate.
- Annex 8: Packaging and labelling information.
- Annex 9: Instructions for use of the medical device

Refer to the following communication issued by SAHPRA:

**Licensing and Regulatory requirements for the manufacture and distribution of medical and respirator masks during COVID-19.**

[MD025 Alternative-licensing-and-regulatory-pathway-for-masks September2020 vF.docx.pdf](#)

[sahpra.org.za](http://sahpra.org.za)

An electronic version of the completed licence application in MS Excel format (manufacturer or distributor application) or MS Word format (wholesaler application).

The curriculum vitae of the Authorised Representative and the Quality Manual (for Manufacturers and Distributors) or the Site Master File (for Wholesalers) must also be submitted.

You are required to submit a PDF version of the licence application, initialled by the Authorised Representative on each page, along with the proof of payment of the licence application fee.

### **3.1.19 Which documents must be submitted with the application when applying for a medical device establishment license with COVID-19 products (this includes Covid-19 test kits and ventilators)?**

All applications should be submitted with a Cover letter that has been prepared on a company letterhead, signed by the authorized representative and it should be dated.

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 and Signed by the authorized representative, for example: Application for a medical device establishment license to manufacture, distribute or wholesale medical devices.

The Cover letter must include a list of the attachments that are submitted with the application, for example:

- Annex 1: License Application
- Annex 2: Proof of Payment
- Annex 3: Curriculum Vitae of the Authorized 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 recognized by SAHPRA.
- Annex 7: SANS certificate or NRCS certificate.
- Annex 8: Packaging and labelling information.
- Annex 9: Instructions for use of the medical device.
- Annex 10: 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**

[MD001-Regulatory-Requirements-for-Medical-Devices-COVID-19-v2-22072020.pdf \(sahpra.org.za\)](#)

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

[MD002-Regulatory-Requirements-for-Serological-Test-Kits-v2-22072020.pdf \(sahpra.org.za\)](#)

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

[MD014-Regulatory-Requirements-for-Molecular-Test-Kits-v1-22072020.pdf \(sahpra.org.za\)](#)

**Regulatory requirements, Technical Specifications, License Conditions and Authorisations for use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19**

[MD010\\_Guidance\\_Rapidly-developed-ventilators\\_v1-26052020.pdf \(sahpra.org.za\)](#)

### 3.1.20 What is a section 36 application?

Refers to section 36 of Medicines and Related 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.

Refer to the publication of this Act on the SAHPRA website:

**Medicines and Related Substances Act no 101 of 1965,**

[Government Gazette Medicines and Devices Act Jun 2017-1.pdf \(sahpra.org.za\)](#)



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

## 4. QUESTIONS ABOUT THE COST OF A MEDICAL DEVICE ESTABLISHMENT LICENSE

### 4.1 How much it costs to apply for a medical device establishment license and how to make the payment?

#### 4.1.1 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*.

The following fees, as published in *Government Gazette No. 1379 on 22 December 2020* are currently applicable:

- a) **Manufacturer's Licence Fee – R25 200**
- b) **Distributor's Licence Fee – R15 000**
- c) **Wholesaler's Licence Fee – R15 000**

- The fee for a medical device establishment licence application is payable upon application and proof of payment should be submitted together with the completed licence application.
- Retention fees are due every year in June from the first anniversary of the date on which the license was issued.
- These fees are applicable to existing license holders who are required to pay these fees in order to retain their license, should the license holder wish to cancel their license then a formal letter has to be submitted by the license holder, to the authority (SAHPRA) indicating that they wish to withdraw their license.

**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*.

#### 4.1.2 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:

Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Account type: CHEQUE ACCOUNT

Account number: 40-5939-2080
Bank: ABSA
Bank branch code: 632005
Swift Code for application fee for a new license application: MD NLIC *company name*
Swift Code for application fee for an amendment application: MD AMD * company name*
Swift code for license collection fee: MD *company name*
Swift code for retention fee: MD RET *company name*
Refer to the latest fees published in the government gazette on: <a href="#">Published-SAHPRA-Fees.pdf</a>
Refer to SAHPRA payment guideline for payment references on: <a href="https://www.sahpra.org.za/wp-content/uploads/2021/06/SAHPRA_Payment_Guideline.pdf">https://www.sahpra.org.za/wp-content/uploads/2021/06/SAHPRA_Payment_Guideline.pdf</a>
<b>4.1.3 What is the process if applicant has paid surplus?</b>
<ol style="list-style-type: none"> <li>1. The applicant must apply for a refund with the finance department.</li> <li>2. The process for refund application follows below.</li> <li>3. Please provide the following information or documents to SAHPRA: <ol style="list-style-type: none"> <li>a) Letter from the company explaining the reason for the refund request</li> <li>b) Proof of payment - (A letter from the bank is not acceptable)</li> <li>c) Valid Tax Clearance Certificate</li> <li>d) Banking details</li> <li>e) Cipro Certificates and ID copies of directors [CK]</li> </ol> <p style="margin-left: 40px;">Or</p> </li> </ol> <p><b>If the refund is requested by an individual:</b></p> <ol style="list-style-type: none"> <li>a) An affidavit or letter stating the reason for refund request</li> <li>b) Certified copy of ID</li> <li>c) Proof of payment</li> <li>d) Banking details</li> </ol>

Please **email refund applications** to [finance@sahpra.org.za](mailto:finance@sahpra.org.za).

**Subject line: Marked “application for refund”**

## 5. QUESTIONS ABOUT SUPPORTING DOCUMENTS

### 5.1 Documents to be submitted with the license application

#### 5.1.1 Who needs to submit a Quality Manual?

- a) Manufacturers
- b) Distributors

A guideline on how to prepare a quality manual is available on the SAHPRA website. To download the guideline, please follow the steps below (refer to Annexure B below for step-by-step guideline on how to download guidelines).

Visit South African Health Products Regulatory Authority (SAHPRA) website at [www.SAHPRA.org.za](http://www.SAHPRA.org.za).

Click on the “health products tab” on the top of the page.

Click on the “medical devices tab”, which is the fourth tab under the health products tab on SAHPRA’s home page.

Select “Guidelines”, which is the third link in the medical devices tab

Select and download “Medical Device Quality manual”

#### 5.1.2 What is an ISO 13485?

A certificate issued by the International Organisation for Standardization to a company that complies with the requirements for a quality management system in the medical device industry.

#### 5.1.3 Who needs to submit ISO 13485 and when will it be compulsory?

The ISO 13485 needs to be submitted by manufactures and distributors and it will be compulsory upon communication from SAHPRA.

## 6. QUESTIONS ABOUT THE RELATIONSHIP BETWEEN SAHPRA AND OTHER REGULATORY BODIES AND PARTNERS

## 6.1 The relationship between SAHPRA and other regulatory bodies and partners.

### 6.1.1 What is the relationship between SAHPRA & NHLS HTA Unit in the regulation of diagnostic devices?

The NHLS conducts performance validation of COVID-19 test kits on behalf of SAHPRA.

Refer to the communication issued by SAHPRA:

**Frequently asked questions: performance evaluation of point-care COVID-19 serology antibody test kits.**

[MD024-FAQs\\_POC\\_COVID-19\\_Antibody\\_Serology\\_Test\\_Kit\\_10092020\\_vF.pdf \(sahpra.org.za\)](#)

### 6.1.2 Will this be limited to Covid-19 diagnostic devices or there will role of the NHLS will be extended further beyond the pandemic?

The role of the NHLS might be extended once registration of medical devices starts, communication will be shared accordingly.

### 6.1.3 What happens during the validation processes: SAHPRA and NHLS

Validation of COVID-19 test kits on behalf of SAHPRA looking at the test performance of the test kit.

NHLS will submit a report to SAHPRA, indicating that it recommends or not recommend the test and section 21 authorisation is issued to the applicant.

Refer to the communication issued by SAHPRA:

**Frequently asked questions: performance evaluation of point-care COVID-19 serology antibody test kits.**

[MD024-FAQs\\_POC\\_COVID-19\\_Antibody\\_Serology\\_Test\\_Kit\\_10092020\\_vF.pdf \(sahpra.org.za\)](#)

### 6.1.4 What is the role of Port Health?

The role of port health is to serve as a first line of defence to protect the citizens of South Africa and visitors against the entry of communicable diseases associated with cross border movement of people, conveyances, baggage, cargo and imported consignments.

### 6.1.5 Where must I go if my products are being held at Port Health?

For any queries related to port health shipment, refer to regulatory compliance unit.

Please contact Mokgadi Daphney Fafudi

Email: [mokgadi.fafudi@sahpra.org.za](mailto:mokgadi.fafudi@sahpra.org.za)

Tel: 012 015 5434

### 6.1.6 What is the role of the medical device unit in relation to Port Health?

The role of the medical device unit is to ensure that all companies who are importing or exporting medical devices are licensed and are listed on the licenses issued register.

#### 6.1.7 What is the relationship between the six jurisdictions recognised by SAHPRA / What role do these authorities play in South African Medical Devices regulatory affairs?

SAHPRA recognises and follows these six jurisdictions as a reliance model which ensures that Class C and D medical devices / IVDs have at least one approval from the six jurisdictions.

SAHPRA still makes the final decision to approve or reject an application based on the South African medical device regulations as well as the Medicines and Related Substances Act 101 of 1965, therefore approval from one of the six jurisdictions does not guarantee approval from SAHPRA as SAHPRA has its own requirements based on the South African market,.

These six jurisdictions recognised by SAHPRA are IMDRF countries, namely:

- Australia
- Canada
- Japan
- United States of America
- Brazil

## 7. GENERAL QUESTIONS

### 7.1 Can someone be Authorized Representative to more than one company?

Yes, It is only acceptable in two scenarios, one for an authorized representative that acts on behalf of the companies within the same address/province and also for companies where the Regulatory oversight is at the head office.

Refer to document:

[Guideline for a License to Manufacture, Import, Export or Distribute Medical Devices and IVDs](#)

[GUIDANCE DOCUMENT: \(sahpra.org.za\)](http://sahpra.org.za)

### 7.2 Can the company apply for different type of licenses on the same premises?

Yes, such as in the case where the company has sub-unit companies or departments within the company.

<b>7.3 Can applicant make any changes of application that was already screened/ evaluated?</b>
No. any changes made after the application is screened will be considered amendments and the applicant will have to follow the amendment application procedure once the application in process has been concluded.
<b>7.4 What happens if one of the shareholders leaves the company?</b>
Not relevant if the shareholder is neither the authorised representative nor the license holder.
<b>7.5 Can establishments (hospitals, pharmacies etc.) use Covid-19 antibody tests to diagnose active Covid-19 cases?</b>
<p>No. These tests determine if the body has started to fight a SARS-CoV2 infection rather than detecting the actual SARS-CoV2 virus.</p> <p>COVID-19 antibody tests are used to guide decision making regarding patient management, decision making regarding the need for quarantine, isolation and contact tracing.</p> <p>Refer to communication issued by SAHPRA:</p> <p><b>Testing for COVID-19</b></p> <p><a href="#">MD003-Testing-for-COVID-19-v1-22072020.pdf (sahpra.org.za)</a></p>

## 8. REFERENCES

The following related documents are referenced:

- 8.1 SAHPGL-MD-06 Guideline for a licence to manufacture, import, export or distribute medical devices and IVDs
- 8.2 16.04 Licence to act as a wholesaler of medical devices and IVDs
- 8.3 Position paper for Amendments
- 8.4 SAHPGL-MD-04: Classification guideline
- 8.5 SAHPGL-MD-05: Medical device Quality Manual
- 8.6 6.21 Licence Application to manufacture, import, distribute or export medical devices
- 8.7 6.22 Licence Application to import, distribute or export medical devices
- 8.8 6.26 Licence Application to Wholesale Medical Device

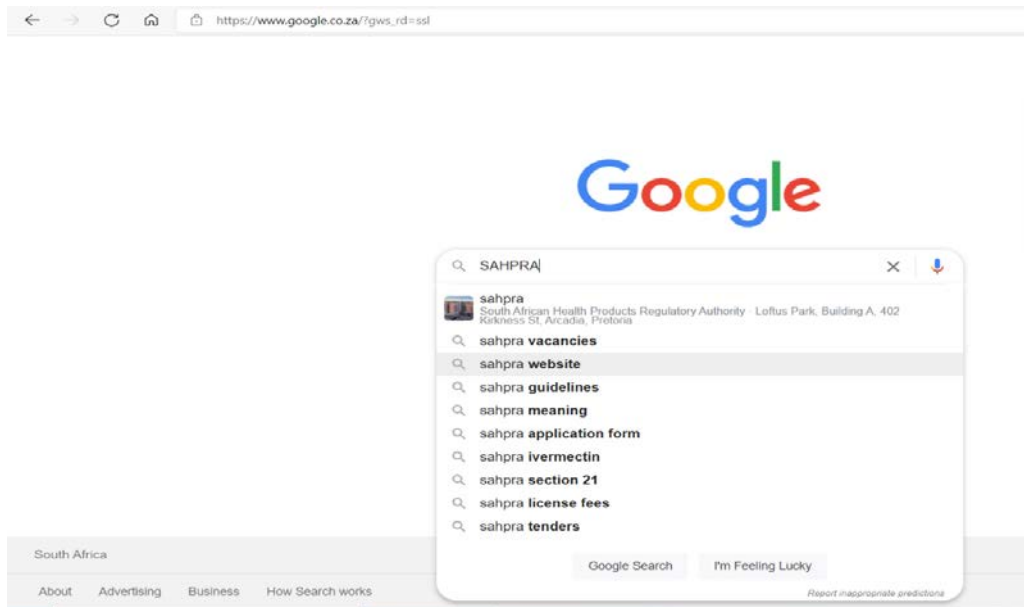
## 9. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline on Questions & Answers: Licensing of Medical Devices/ IVDs, old document number 8.10. It will be reviewed on this timeframe or as and when required.

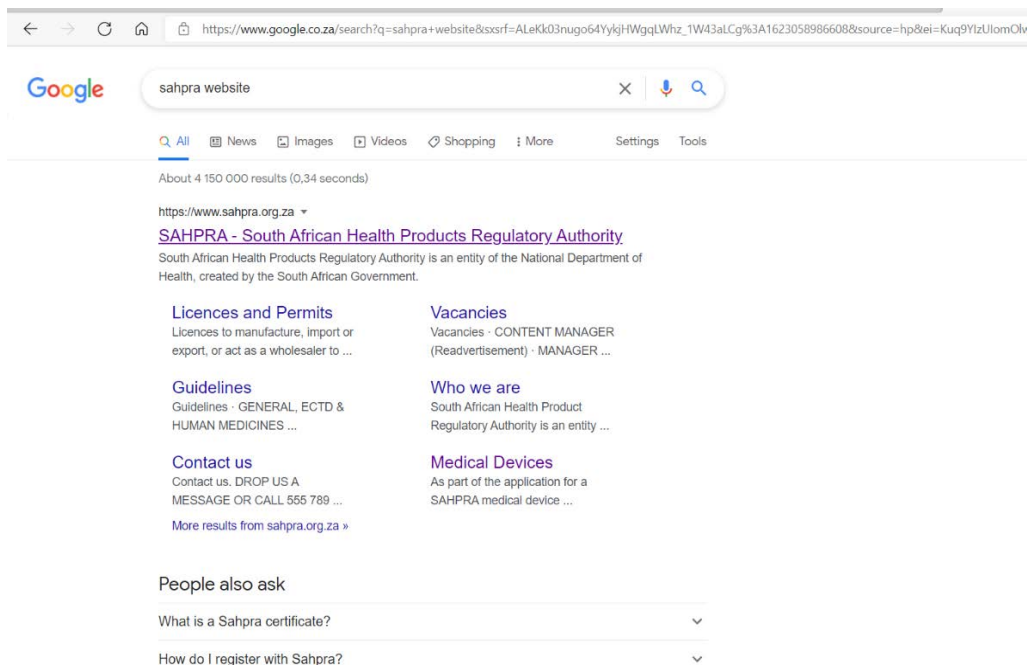
## 10. ANNEXURES

### 10.1 Annexure A: Step by step guideline (Step 1 – 6)

**Step 1: type ‘SAHPRA Website’ on your search engine.**

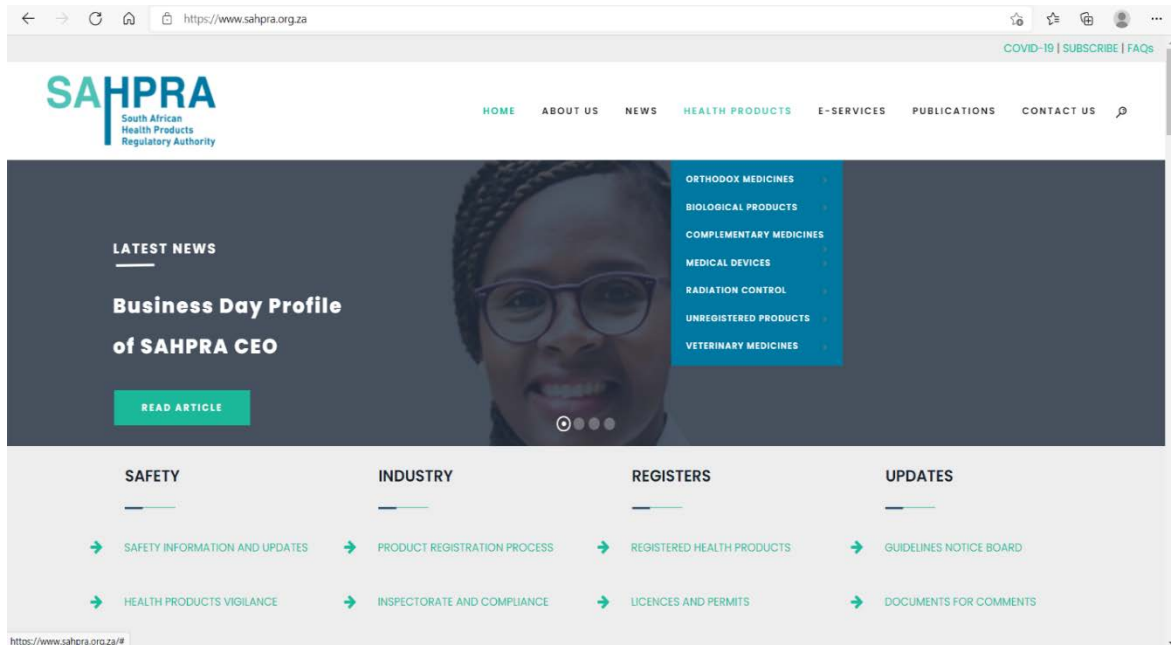


**Step 2: Select the SAHPRA link**

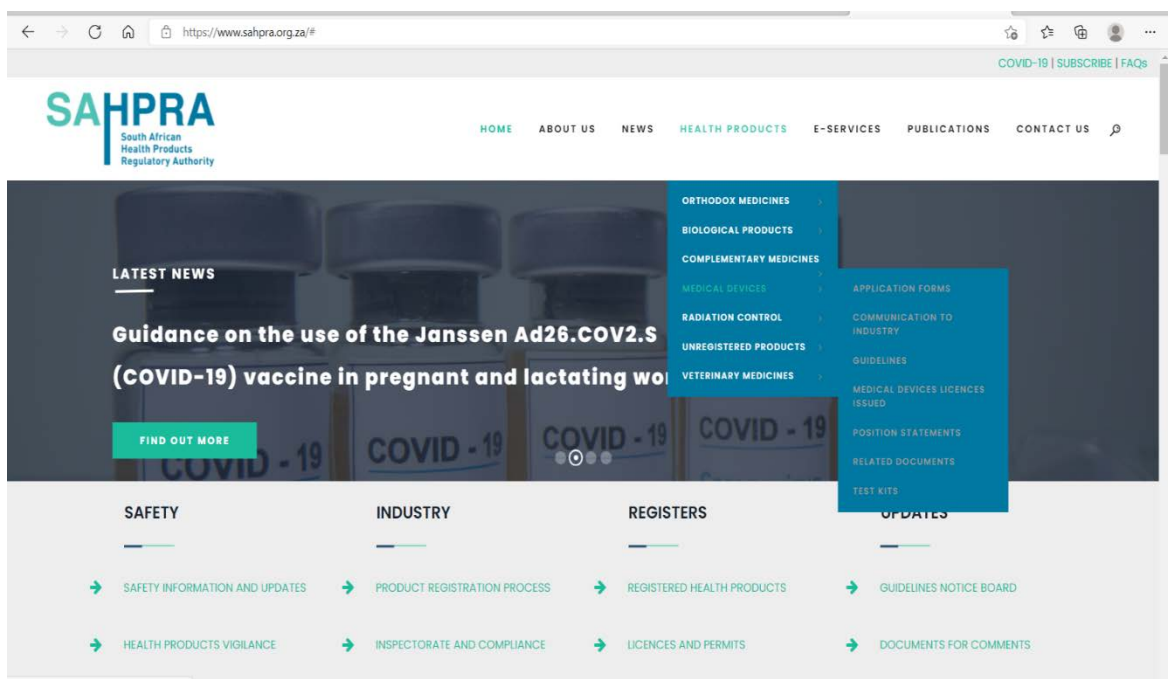




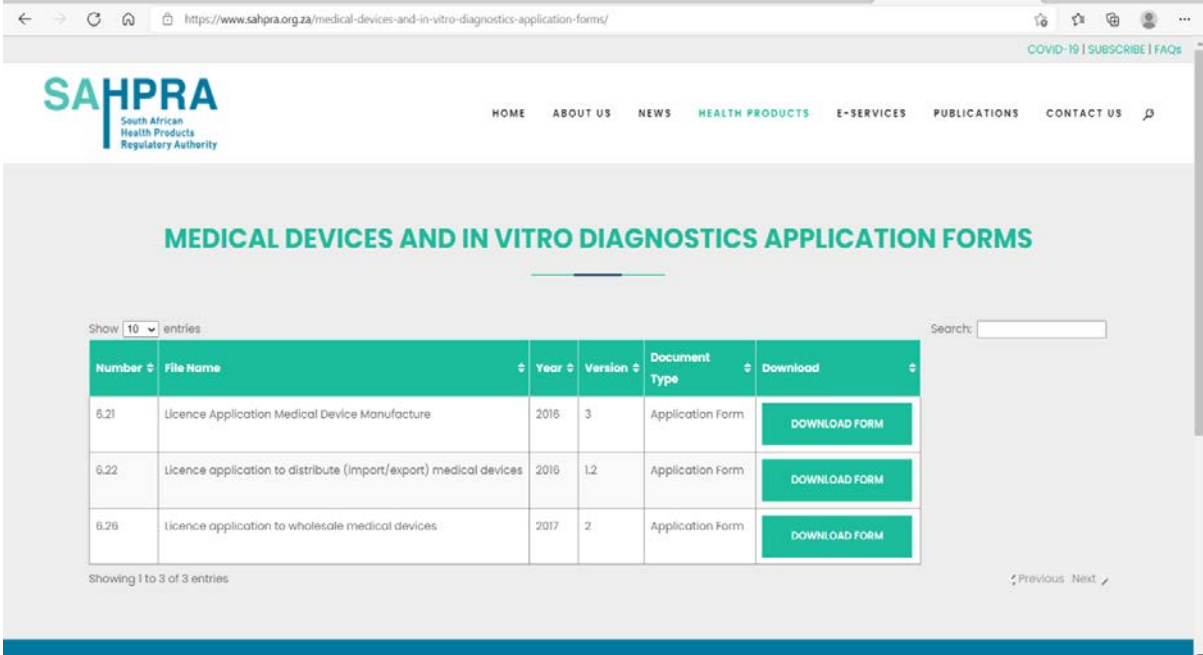
**Step 3: On the SAHPRA website, select the health products tab.**



**Step 4: Select Medical devices tab > application forms**



**Step 5: Select the appropriate application form. Download and complete the application form.**



The screenshot shows the SAHPRA website interface. The main heading is 'MEDICAL DEVICES AND IN VITRO DIAGNOSTICS APPLICATION FORMS'. Below the heading is a table with the following data:

Number	File Name	Year	Version	Document Type	Download
6.21	Licence Application Medical Device Manufacture	2016	3	Application Form	DOWNLOAD FORM
6.22	Licence application to distribute (import/export) medical devices	2016	1.2	Application Form	DOWNLOAD FORM
6.26	Licence application to wholesale medical devices	2017	2	Application Form	DOWNLOAD FORM

Below the table, it says 'Showing 1 to 3 of 3 entries'. There is also a search bar and navigation links for 'Previous' and 'Next'.

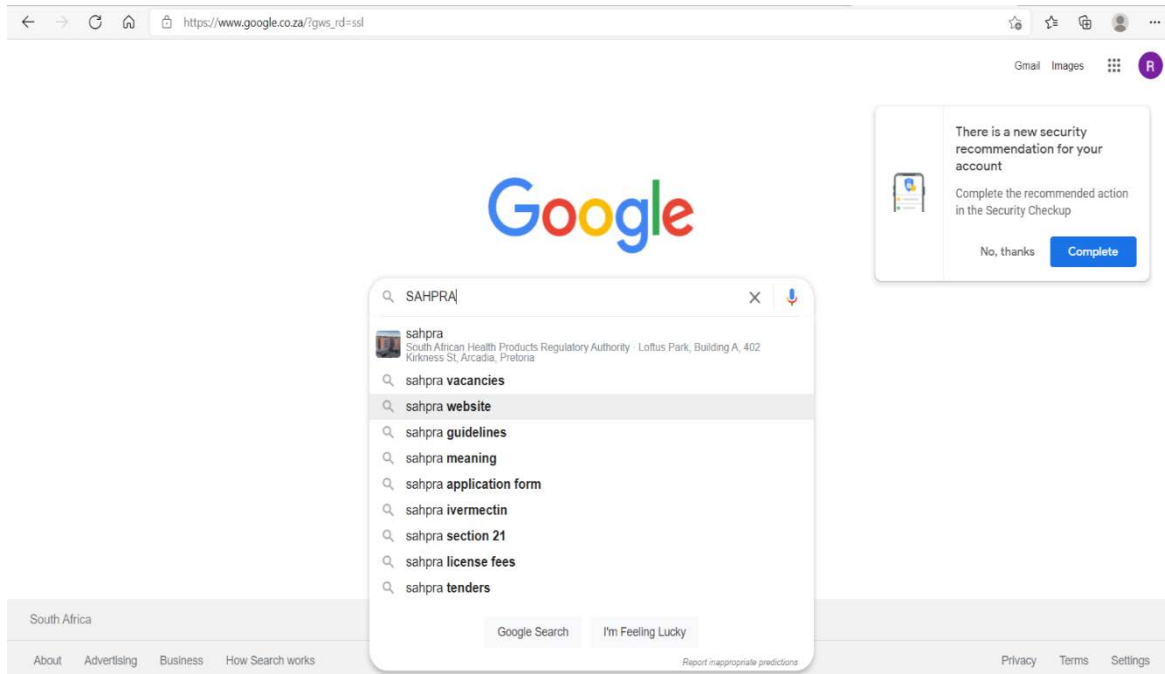
**Step 6: Submit the application form and supporting documents to: [mdcovid@sahpra.org.za](mailto:mdcovid@sahpra.org.za) for COVID-19 related applications and [mdadmin@sahpra.org.za](mailto:mdadmin@sahpra.org.za) for business as usual applications**

**NB: Supporting documents required:**

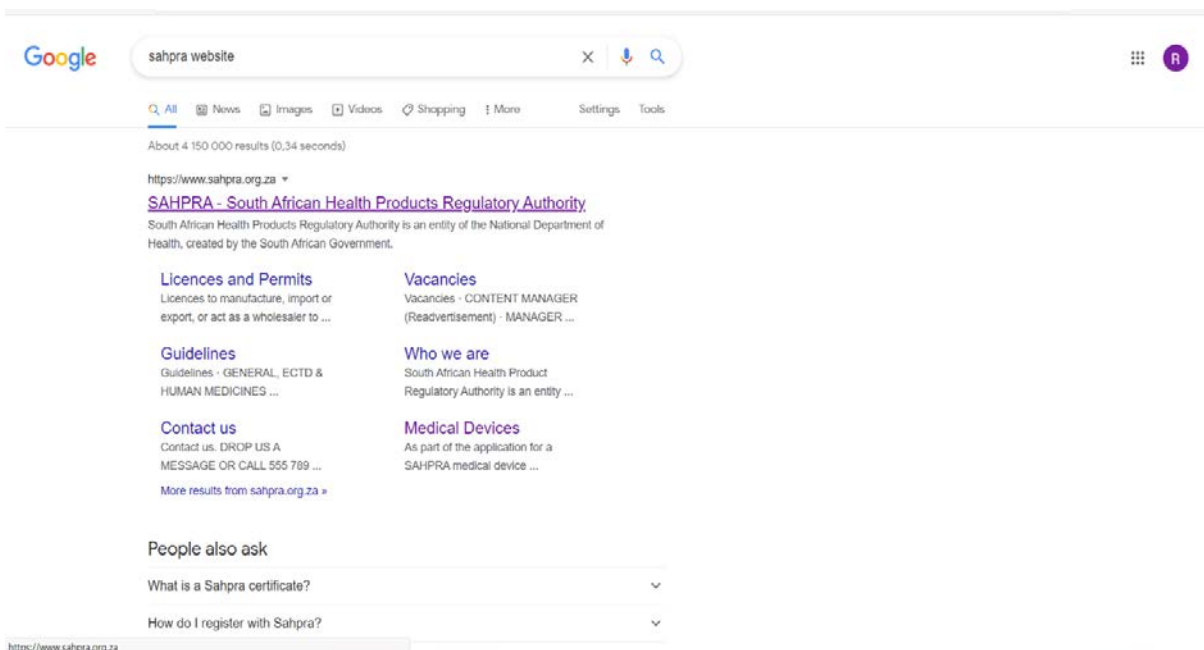
1. Cover letter
2. Proof of payment (application fee)
3. Site master file for wholesale application
4. Quality manual for distributor or manufacturer application
5. CV of the authorised representative
6. PDF application form that is initialled on each page by the authorised representative
7. Declaration on the application form must be signed by the authorised representative

## 10.2 Annexure B: Step-by- step process on how to download guidelines required for a Medical Device Establishment License application (Step 1 – 6)

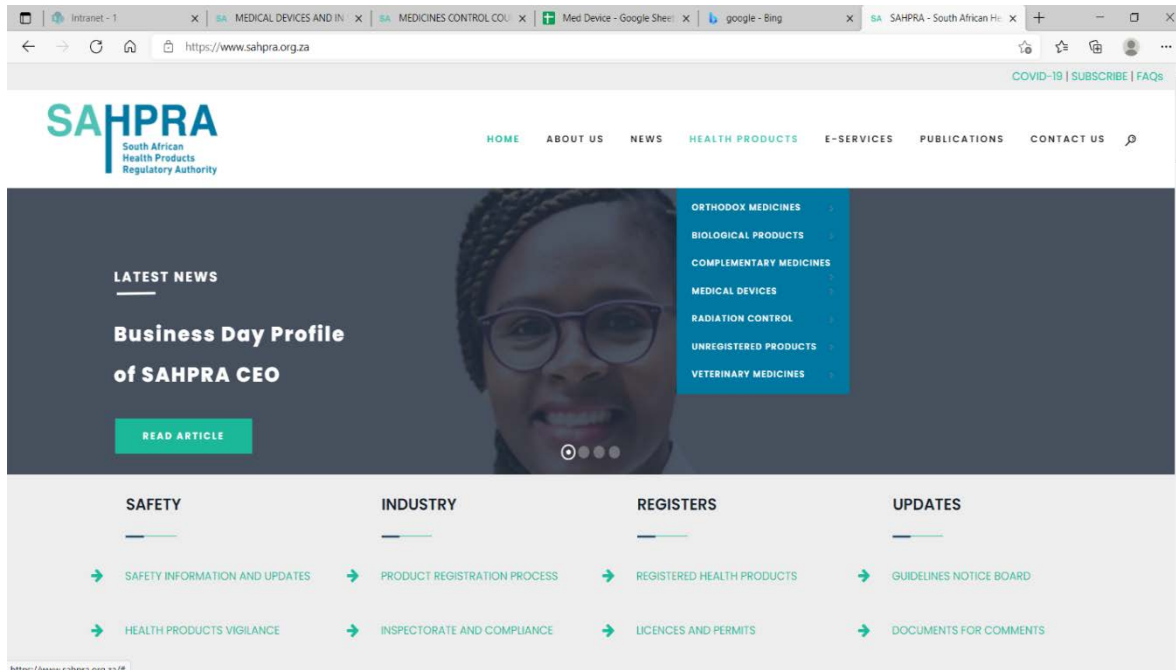
**Step 1: type ‘SAHPRA Website’ on your search engine.**



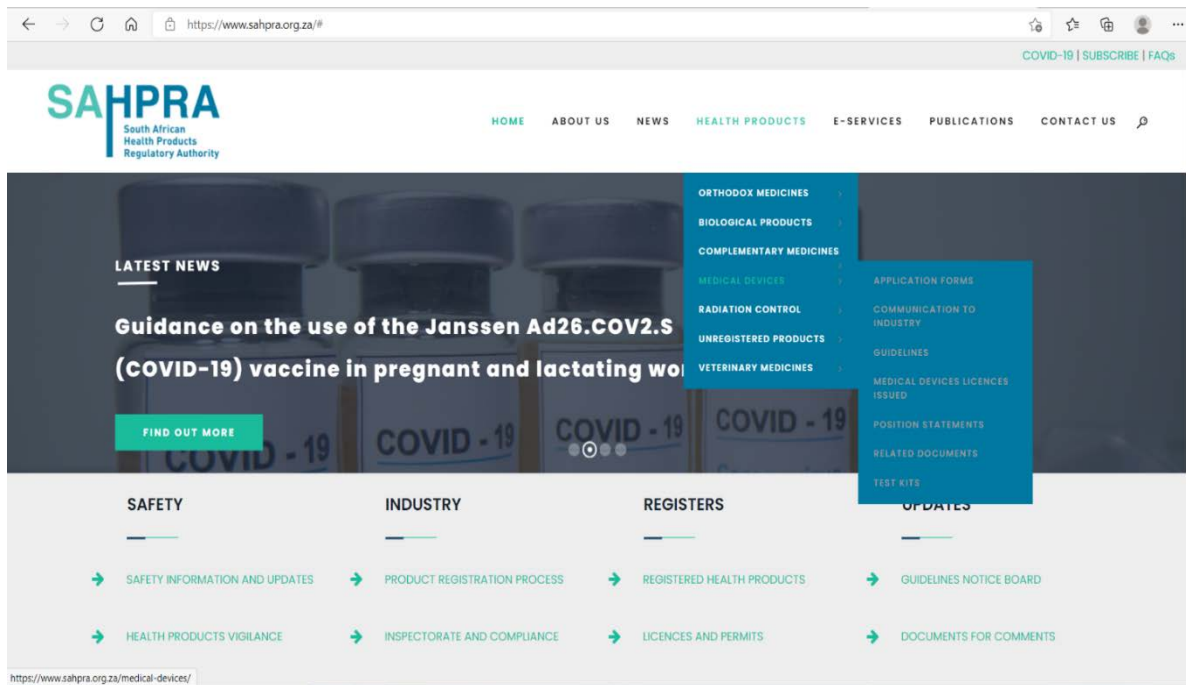
**Step 2: Select the SAHPRA website:**

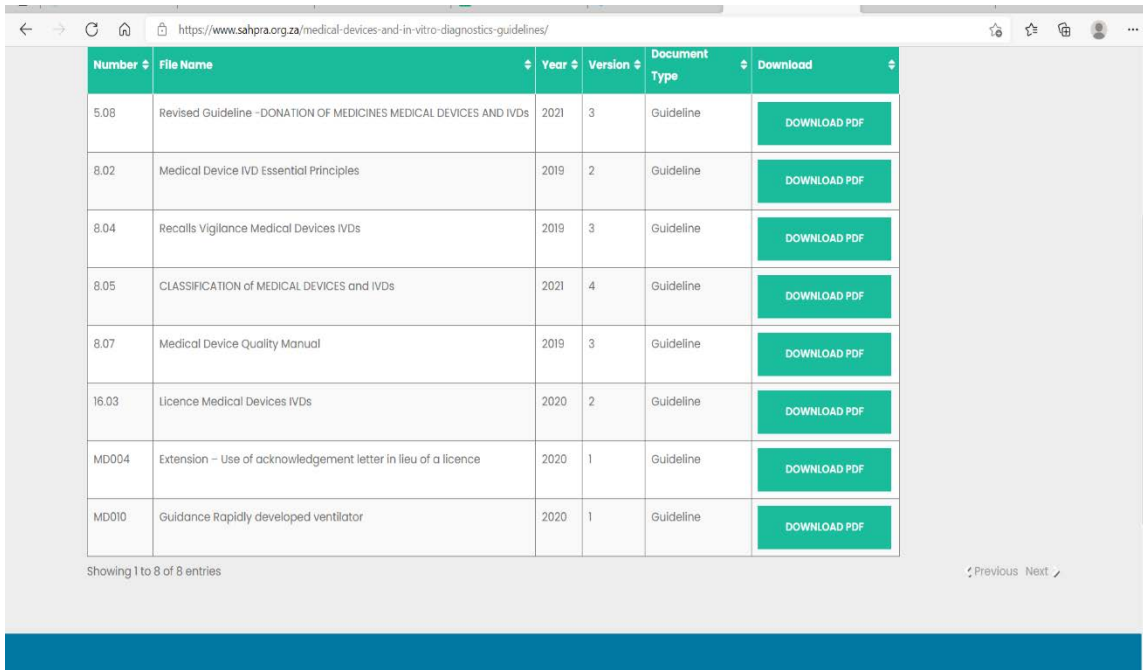


**Step 3: On the SAHPRA website, select the health products tab.**



**Step 4: Select medical devices tab > guidelines**



**Step 5: download the applicable guideline to use when compiling the supporting documents.**


The screenshot shows a web browser window with the URL <https://www.sahpra.org.za/medical-devices-and-in-vitro-diagnostics-guidelines/>. The browser displays a table with 8 rows of guidelines. Each row includes a number, file name, year, version, document type, and a 'Download PDF' button. The table is as follows:

Number	File Name	Year	Version	Document Type	Download
5.08	Revised Guideline – DONATION OF MEDICINES MEDICAL DEVICES AND IVDs	2021	3	Guideline	DOWNLOAD PDF
8.02	Medical Device IVD Essential Principles	2019	2	Guideline	DOWNLOAD PDF
8.04	Recalls Vigilance Medical Devices IVDs	2019	3	Guideline	DOWNLOAD PDF
8.05	CLASSIFICATION of MEDICAL DEVICES and IVDs	2021	4	Guideline	DOWNLOAD PDF
8.07	Medical Device Quality Manual	2019	3	Guideline	DOWNLOAD PDF
16.03	Licence Medical Devices IVDs	2020	2	Guideline	DOWNLOAD PDF
MD004	Extension – Use of acknowledgement letter in lieu of a licence	2020	1	Guideline	DOWNLOAD PDF
MD010	Guidance Rapidly developed ventilator	2020	1	Guideline	DOWNLOAD PDF

Showing 1 to 8 of 8 entries

Previous Next

**Step 6: Submit the application form and supporting documents to: [mdcovid@sahpra.org.za](mailto:mdcovid@sahpra.org.za) for COVID-19 related applications or [mdadmin@sahpra.org.za](mailto:mdadmin@sahpra.org.za) for business as usual applications.**

**NB: Supporting documents required:**

1. Cover letter
2. Proof of payment (application fee)
3. Site master file for wholesale application
4. Quality manual for distributor or manufacturer application
5. CV of the authorised representative
6. PDF application form that is initialled on each page by the authorised representative
7. Declaration on the application form must be signed by the authorised representative
8. Copy of existing license and cover letter