WESGRO

Overview of Covid-19 health products category & regulatory requirements

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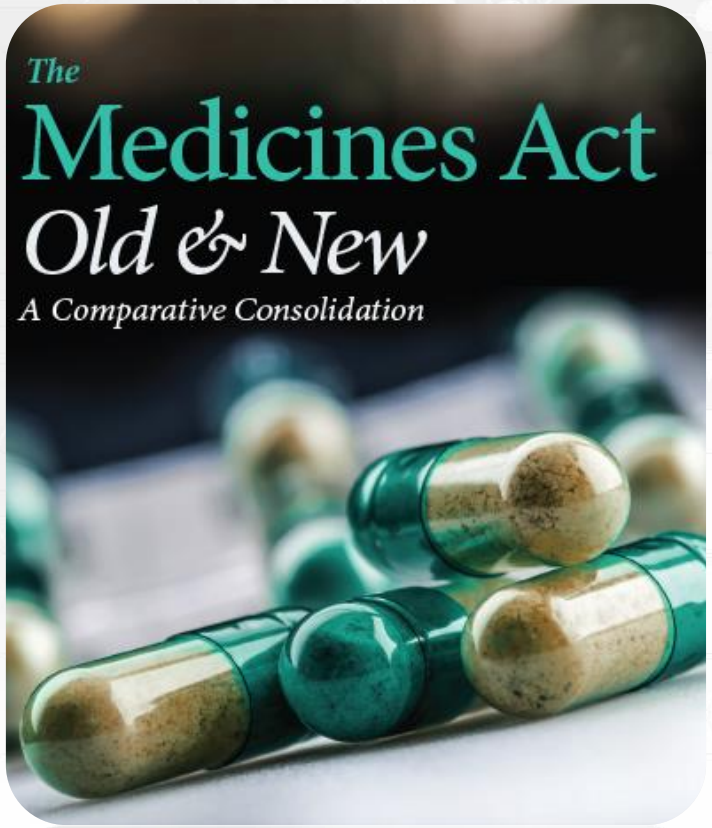
SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Act 72 of 2008 and Act 14 of 2015

- **Provides for transition of MCC to SAHPRA and the establishment of a new regulatory authority**
- **South African Health Products Regulatory Authority (SAHPRA)**
- **SAHPRA established in February 2018**



General Regulations (for Medicines):
Publication 25 August 2017, Government Gazette No 41064, No. 859

Regulations for Medical Devices & IVDs:
Publication 9 December 2016, Government Gazette No 40480, No 1515

SAHPRA

- World Health Organization Global Model
- International Medical Device Regulators Forum
- Phased Approach

STEP 1:

- **Licensing of**
- **Medical Device Establishments**

STEP 2:

- **Registration of**
- **Medical Devices**

Regulations for Medical Devices

SUPPLY OF MEDICAL DEVICES

1. Definitions
2. Manner and conditions for allowing international tendering
3. Importation of medical devices into Republic
4. Transmission of medical devices through Republic

REGISTRATION OF MEDICAL DEVICES

5. **Classification of medical devices**
6. Labelling of medical devices
7. Instructions for use of a medical device which is not an IVD
8. Instructions for use of an IVD
9. **Application for registration of a medical device**
10. Information that must appear in register for medical devices
11. Application for amendment to register for medical devices
12. Certificate of registration

PERMITS, LICENSING AND AUTHORISATION

13. **Licence to manufacture, distribute or wholesale medical devices**
14. Period of validity and renewal of licence issued in terms of regulation 13

Regulations for Medical Devices

MANAGEMENT OF MEDICAL DEVICES

15. Parts and components
16. Destruction of medical devices
17. **Conduct of clinical trial of medical devices**
18. **Adverse event reporting and vigilance for medical devices**
19. Custom made medical devices
20. Record of implantable medical devices and custom made medical devices
21. **Advertising of medical devices**
22. Appraisal and exhibition of medical devices

INVESTIGATIONS, OFFENCES AND PENALTIES

23. Investigations
24. Method of taking samples during investigation, certificate to be issued and reporting of analysis results
25. Compliance with requirements
26. **Offences and penalties**

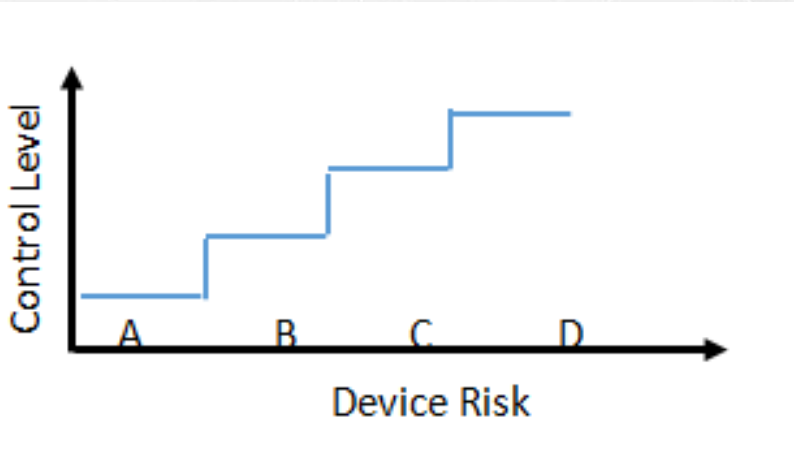
TRANSITIONAL ARRANGEMENTS

27. Transitional arrangements - unregistered medical devices

Classification of Medical Devices

- Classification is based on design and intended use
- Manufacturer/Distributor is responsible for indicating the classification of each medical device, listed on licence application form
- Where the classification of a medical device or IVD places it in more than one class it will be placed in the higher class
- Classification of medical devices will be confirmed by SAHPRA at the time of registration

- Class A – Low Risk
- Class B – Low-moderate Risk
- Class C – Moderate-high Risk
- Class D – High Risk



Position Paper – Exemption Class A

Section 22C(1)(b) of the Act requires all Medical Device establishments doing business in South Africa to obtain a licence from the MCC to manufacture, distribute and wholesale medical devices.

- Manufacturers, distributors and wholesalers of **Class A medical devices**, which are considered to have a ***measuring function*** or which are required to be ***sterile***, must apply for a medical device establishment licence.

- Manufacturers, distributors and wholesalers of ***any other*** **Class A** medical device **need not apply** for a medical device establishment licence until further notice in this regard is issued, but nothing prohibits them from applying for such a licence.

Regulatory Requirements for PPE

Joint Communication to Stakeholders

Regulatory Status of Equipment Being Used to Help Prevent Coronavirus (COVID-19)

1. In the wake of the coronavirus (COVID-19) crisis, and with the increase in the need and use of devices and equipment to prevent the spread of coronavirus, including hand sanitisers and personal protective equipment (PPE), it is paramount that the regulatory status of such devices and equipment is clearly articulated and disseminated to the industry.

2. To assist manufacturers during the COVID-19 crisis, the South African Bureau of Standards (SABS) in collaboration with the South African Health Products Regulatory Authority (SAHPRA), the National Regulator for Compulsory Specifications (NRCS), and the Department of Trade and Industry will provide support to manufacturers and distributors in respect of applicable standards

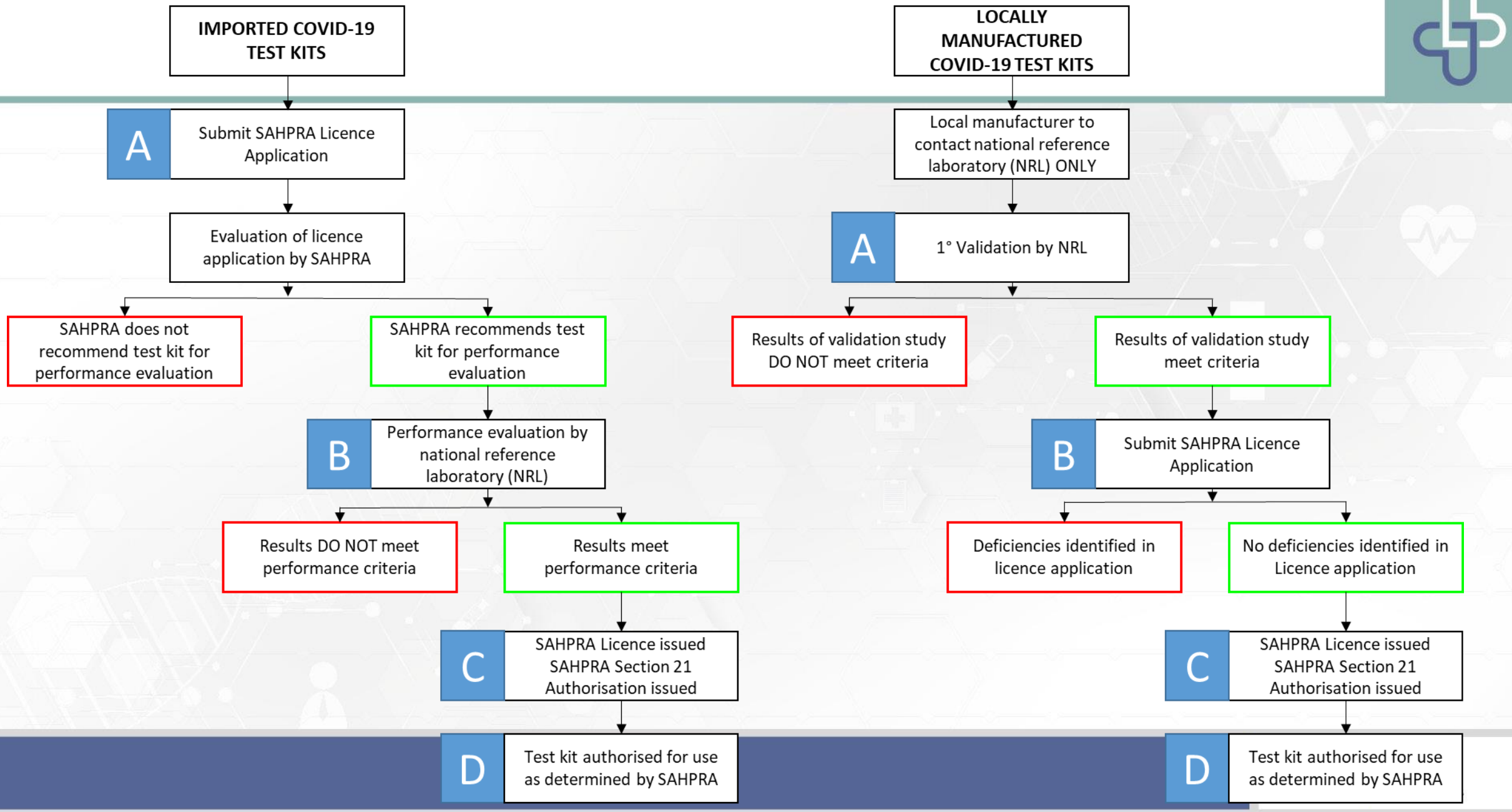
Regulatory Requirements for Masks

	Cloth mask	Non-Sterile Medical (Surgical) Mask	Non-Sterile Medical (Surgical) Mask	Sterile Medical (Surgical) Mask	Dust Mask	Respirator Mask	Respirator Mask (Particle Filtering Half Mask
							
Examples		1-ply, 2-ply or 3-ply masks	3-ply masks	3-ply masks		N95, KN95	N95, KN95
Classification	Non-medical General	Non-medical General	Class A medical device	Class A medical device (Sterile)	Non-medical General	Class B medical device	Non-medical e.g. mining industry
SAHPRA manufacturer, distributor, wholesaler licence	No	No	No Exemption from licensing requirement for non-sterile Class A medical devices	Yes	No	Yes	No
NRCS sales permit/ authorisation (LOA)	No	No	No	No	No	Yes	Yes
Specification/ Standards/ Other Legislation	None Department of Health guideline on the "Use of Cloth Face-Masks by Members of the General Public in South Africa during the COVID-19 Pandemic"	None	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014), in terms of packaging and labelling.	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014), in terms of packaging and labelling.	None	Yes. SANS 1866-2 2018 VC8072:2011 - Compulsory Specification for respiratory protective devices	Yes. SANS 1866-2 2018 VC8072:2011 - Compulsory Specification for respiratory protective devices

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Regulatory Requirements for Gloves

- Gloves fall into different regulatory groups depending on the intended use of the gloves.
- If the gloves are intended to be used by healthcare professionals to protect the patient during a medical examination or during a surgical procedure, these examination gloves or surgical gloves are regulated as medical devices controlled under the ambit of the Medicines Act; and fall within the mandate of SAHPRA.
- Examination non-sterile gloves are classified as Class A medical devices and surgical sterile gloves are classified as Class B medical devices.
- Manufacturers, distributors and wholesalers of Class B surgical sterile gloves must comply with the SAHPRA licensing requirements in point (20).
- Sterile and non-sterile gloves must equally comply with and be tested according to the test methodology provided in:
    - SANS11193-1:2010 “Single-use medical examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution” and
    - SANS68:2003 “Singleuse sterile rubber surgical gloves - Specification” or equivalent international standards.
- General gloves used to protect the wearer (use in laboratories or for protective purposes) must also comply with the relevant SANS or equivalent international standards


IMPORTED COVID-19 TEST KITS
A
Submit SAHPRA Licence Application
Evaluation of licence application by SAHPRA
SAHPRA does not recommend test kit for performance evaluation
SAHPRA recommends test kit for performance evaluation
B
Performance evaluation by national reference laboratory (NRL)
Results DO NOT meet performance criteria
Results meet performance criteria
C
SAHPRA Licence issued SAHPRA Section 21 Authorisation issued
D
Test kit authorised for use as determined by SAHPRA
LOCALLY MANUFACTURED COVID-19 TEST KITS
Local manufacturer to contact national reference laboratory (NRL) ONLY
A
1° Validation by NRL
Results of validation study DO NOT meet criteria
Results of validation study meet criteria
B
Submit SAHPRA Licence Application
Deficiencies identified in licence application
No deficiencies identified in Licence application
C
SAHPRA Licence issued SAHPRA Section 21 Authorisation issued
D
Test kit authorised for use as determined by SAHPRA

TEST KITS: MD002 Serological / MD014 Molecular

1. Cover letter on company letter indicating intention to apply for a new SAHPRA licence.
2. Completed licence application form in MS Excel format
3. Licence Application (6.21 Manufacturer / 6.22 Distributor / 6.26 Wholesaler)
4. Completed licence application form in PDF format, including signed declaration and initialed on each page by the Authorised Representative)
5. Proof of Payment (Manufacturer: R 23 980 / Distributor or Wholesaler: R 14 300)
6. Curriculum Vitae of the Authorised Representative
7. Quality Manual (Applicable to Manufacturers/Distributors) or Site Master File (Applicable to Wholesalers) - Evidence of ISO13485:2016 certification
8. **Technical dossier**
9. **Primary Validation Study – Report**
10. **Instructions for Use**
11. **Copy of labelling and packaging**

Communication to Stakeholders

MD001 - Regulatory Requirements for Medical Devices COVID-19 v2 – 22072020

MD002 - Regulatory Requirements for Serological Test Kits v2 – 22072020

MD003 - Testing for COVID-19 v1 – 22072020

MD004 - EXTENSION - Use of Acknowledgement Letter in Lieu of Licence v1 – 31032020

MD005 - Expedited Regulatory Pathways for Medical Devices v1 – 22072020

MD006 - Laboratory Testing and Use of COVID-19 Serological Test Kits v1 – 22072020

MD007 - Specifications Serological Test kits v2 – 22072020

MD008 - ISO Standards for Medical Devices and Protective Clothing v1 – 22072020

MD009 - Alternative_Regulatory_Licensing_Requirements_Alcohol-based_sanitisers v1 – 03072020

MD010 - Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19 v1 - 26052020

Communication to Stakeholders

MD011 - Licence Conditions for COVID-19 Serological Test Kits v1 – 22072020

MD012 - Notice of Contravention of Act 101 of 1965 v1 – 22072020

MD013 - Process Flow Locally Manufactured COVID-19 Test Kits v1 – 22072020

MD014 - Regulatory Requirements for Molecular Test Kits v1 – 22072020

MD015 - Process Flow Imported COVID-19 Test Kits v1 – 22072020

MD016 - Conditions of Use COVID-19 Serological Test Kits v1 - 22072020

MD017 - Technical Review Application COVID-19 Molecular Test Kits v1 – 22072020

MD018 - Specifications Molecular Test kits v1 – 22072020

MD019 - Processing of licence applications v1 – 22072020

MD020 - Certificate of Free Sale_v2 22072020

LICENCE APPLICATIONS

MDCOVID@SAHPRA.ORG.ZA

- Pending applications
- TRIAL - Dash board

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Reporting to SAHPRA

- Report any activities suspected to be in contravention to the Medicines and Related Substances Act, 1965 (Act 101 of 19645)

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Thank You