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 and conformity assessments to assist them to prepare for the licensing and approval process.

3. The SABS is making available a quick-track mechanism for the issue of letters of conformance (LoC) in terms of the SABS Product Certification (Mark) Scheme, for the products related to this communique. An LoC can be used during the registration as a supplier for the National procurement programme of Covid-19 related equipment.

4. The SABS also provides Consignment Inspection releases for batches of product related to this communique, whether they are imported or manufactured locally. This can assist both bulk-buyers and sellers of products to confirm that products comply with requirements. Enquiries can be directed to gorden.seopa@sabs.co.za and reza.shah@sabs.co.za.

Hand Sanitisers, Hand Gels, Surface Sanitisers, Antiseptics, Disinfectants and Germicides

5. Sanitising products may fall into various regulatory groups depending on the:
    a. Application surface (human skin or inanimate surface)
    b. Environment the sanitiser is used in (place of use)
    c. Intended use and function; and
    d. Composition
6. Hand sanitisers (handrubs) are generally regarded as "Rub" or "Leave on" products primarily used to sanitise the skin, when soap and water are not available, and are left on and not rinsed off with water.
7. Hand sanitisers are consider to be general consumer products controlled under the ambit of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), hereafter referred to as the FCD Act, and fall within the mandate of the Directorate: Environmental Health within the National Department of Health, if:
    a. they do not contain a substance listed in the Schedules to the Medicines and Related Substances Act, 1965 (Act 101 of 1965, as amended), hereafter referred to as the Medicines Act; and
    b. they make general low level claims against bacteria (for example, kills 99.9 % of bacteria).
8. Handrubs must comply with the relevant South African National Standards (SANS) or equivalent international standards well as the Legal Metrology Act, 2014 (Act 9 of 2014), in terms of packaging and labelling.
9. Alcohol-based hand sanitisers must additionally be tested according to the test methodology provided in SANS 490:2013 "Disinfectant alcohol-based handrub".
10. Products primarily claiming to kill germs, disinfect or sanitise using an active antimicrobial ingredient, such as the hand sanitisers used in hospitals, are controlled as medicines under the ambit of the Medicines Act; and fall within the mandate of SAHPRA.
11. Antiseptic and anti-bacterial products specifically for use as surgical scrubs in operating theatres and used on human skin in hospital operating rooms, ICUs, burn units, and catheterization laboratories, which make claims to treat / prevent infection, are controlled as medicines under the ambit of the Medicines Act; and fall within the mandate of SAHPRA.
12. Disinfectants and germicides used on inanimate surfaces in low risk areas within the home, public venues (schools, restaurants), health institutions, health professional consulting rooms and clinics are controlled under the ambit of the FCD Act, and fall within the mandate of the Directorate: Environmental Health within the Department of Health. These products must comply with the requirements of the "Compulsory specification for chemical disinfectants

VC8054" as set out by the NRCS, the Legal Metrology Act, 2014 (Act 9 of 2014) as well as all relevant SANS.

13. Disinfectants, antiseptics and germicides used on inanimate surfaces in areas of high risk (hospital operating rooms, intensive care units (ICUs), burn units, Catheterization Laboratories), are controlled as medical devices under the ambit of the Medicines Act; and fall within the mandate of the South African Health Products Regulatory Authority (SAHPRA).
14. Disinfectants used to clean medical instruments are controlled as medical devices under the ambit of the Medicines Act; and fall within the mandate of SAHPRA.
15. Where the intended use or claim for a product mentioned above lies in both low and high risk areas, the product will fall under the regulatory ambit of the Medicines Act and fall within the mandate of SAHPRA.

General, Medical (Surgical) Face Masks and Respiratory Protective Devices (Respirators)

16. Face masks fall into different regulatory groups depending on the type of face mask and intended use of the face mask: General, Medical (Surgical) Masks Non-Sterile, Medical (Surgical) Masks Sterile and Respirator Masks. Refer to infographic in Annexure 1 for a summary of the types of masks, regulatory requirements and intended purpose.
17. General face masks, including textile or fabric cloth face masks are not considered protective against respiratory viruses and may not make claims to protect the user or the public from infective agents. The National Department of Health has published guidance on "Use of Cloth Face-Masks by Members of the General Public in South Africa during the COVID-19 Pandemic".[1]
18. General face masks, when not intended for use in a clinical environment, and where no claim is made for protection from viruses, do not fall under the regulatory control of the Medicines Act or the National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008), hereafter referred to as the NRCS Act.
19. Non-sterile medical (surgical) masks and sterile medical (surgical) masks such as a 3-ply mask intended for use in a clinical environment are classified as **Class A Medical Devices** and are controlled under the ambit of the Medicines Act, and fall within the mandate of SAHPRA.
20. A medical device may only be manufactured, imported, exported, distributed or wholesaled by a medical device establishment that holds a valid medical device establishment licence issued by SAHPRA, in terms of Section 22C(1)(b) of the Medicines Act.

[1] http://www.health.gov.za/index.php/component/phocadownload/category/631#

21. However, manufacturers, distributors and wholesalers of non-sterile Class A medical devices are excluded from the licensing requirement stated in point (20).[2] Therefore, manufacturers, distributors and wholesalers of non-sterile surgical masks do not require a section 22C(1)(b) licence from SAHPRA.
22. Manufacturers, distributors and wholesalers of sterile surgical masks must comply with the licensing requirements in point (20).
23. The relevant application forms and guidelines for licensing of a medical device establishment can be accessed via the SAHPRA website. [3]
24. Sterile and non-sterile surgical masks must be tested according to, and be certified against, the SANS 1866-1:2018 "Medical Devices Part 1: Medical Face Masks" - or equivalent international standards, as well as the Legal Metrology Act, 2014 (Act 9 of 2014), in terms of packaging and labelling. The SAHPRA may declare conditional exclusions of and modifications to the tests of SANS 1866-1:2018 for South African manufacturers.
25. A respirator mask such as an N95 mask, intended for use in a clinical environment, is classified as a **Class B Medical Device** by SAHPRA and is controlled under the ambit of both the Medicines Act and the NRCS Act.
26. Manufacturers, distributors and wholesalers of respirator masks must comply with SAHPRA's licensing requirements in point (20).
27. Manufacturers, importers and distributors of respirator masks must also apply for pre-approval from the NRCS to ensure compliance against the minimum requirements set out in the Compulsory Specification for respiratory protective devices - VC8072:2011, as published by Government Notice No. R. 407 (Government Gazette No. 34272) of 13 May 2011 and the SANS 1866-2:2018 "Medical devices Part 2: Medical Respirators".
28. Therefore, a respirator mask, intended for use in a clinical environment, requires pre-approval from the NRCS, and the manufacturer, distributor or wholesaler of said mask, requires licensing approval from SAHPRA.
29. Manufacturers, importers and distributors of respirator masks and particle filtering half masks (dust masks) intended for use in a non-clinical environment must apply for pre-approval from the NRCS to ensure compliance against the minimum requirements set out in the Compulsory Specification for respiratory protective devices - VC8072:2011, as published by Government Notice No. R. 407 (Government Gazette No. 34272) of 13 May 2011.
30. Depending on the intended use of the mask and the environment in which the mask is used, respiratory protective devices are also subjected to the provisions of the following Acts:

[2] https://www.sahpra.org.za/wp-content/uploads/2019/09/9.106_Class_A_Medical_Devices_Sept17_v1.pdf
[3] https://www.sahpra.org.za/medical-devices/

- National Regulator for Compulsory Specifications Act, 2008 (Act of 2008)
- Mine Health and Safety Act, 1996 (Act 29 of 1996)
- Occupational Health and Safety Act, 1993 (Act 85 of 1993)

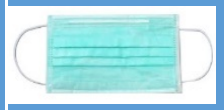
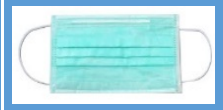
31. Face masks certified against the above-mentioned standards can be identified by the standard marked on the package and on the mask itself.

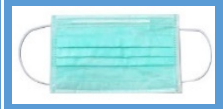
Surgical, Examination and General Gloves

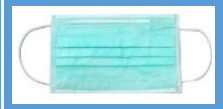
32. Gloves fall into different regulatory groups depending on the intended use of the gloves.
33. If the gloves are intended to be used by healthcare professionals to protect the patient during a medical examination or during a surgical procedure, these examination gloves or surgical gloves are regulated as medical devices controlled under the ambit of the Medicines Act; and fall within the mandate of SAHPRA.
34. Examination non-sterile gloves are classified as Class A medical devices and surgical sterile gloves are classified as Class B medical devices.
35. Manufacturers, distributors and wholesalers of Class B surgical sterile gloves must comply with the SAHPRA licensing requirements in point (20).
36. 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 “Single-use sterile rubber surgical gloves - Specification” or equivalent international standards.
37. 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

DR B SEMETE-MAKOKOTLELA	MR EDWARD MAMADISE	MS JODI SCHOLTZ
CEO OF SAHPRA	CEO: NRCS	LEAD ADMINISTRATOR: SABS
26 MAY 2020	26 MAY 2020	26 MAY 2020

ANNEXURE A: SUMMARY OF FACE 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

	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
							
Intended use and purpose	Non-medical environment Respiratory hygiene and extension of coughing and sneezing etiquette	Non- medical environment Respiratory hygiene and extension of coughing and sneezing etiquette Capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large-particle droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Non-medical and Non-hazardous environments One way protection only capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Reduces wearer's exposure to particles including small particle aerosols and large droplets Protects the patient from the wearer's respiratory emissions.	Non-medical environment Hazardous environment Reduces wearer's exposure to particles including small particle aerosols and large droplets
Face seal fit	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Tight-fitting	Tight-fitting
Filtration	None	None	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	None	Filters out at least 95% of airborne particles including large and small particles	Filters out at least 95% of airborne particles including large and small particles

	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
							
Use limitations	Wash and iron after each use Discard when mask is worn out or damaged	Single-use only Disposable	Single-use only Disposable Discard after each patient encounter.	Single-use only Disposable Discard after each patient encounter.	Disposable	Single use only Disposable Discard after each patient encounter.	Disposable Discard when mask is damaged or deformed; or breathing becomes difficult