MEDIA RELEASE

Know your coronavirus mask:
Highest safety, quality and efficacy standards essential for COVID-19 response

The public and everyone involved in eliminating the SARS-CoV-2 virus needs to be vigilant of the standards and guidelines that apply to products used to prevent, diagnose and treat COVID-19.

Since the new coronavirus reached South Africa, the procurement and manufacture of crucial items including sanitisers, masks, gloves and other personal protective equipment (PPE), and tests have been approached with urgency.

This has opened doors for new local and international manufacturers and suppliers who wish to take part in the response to the pandemic. However, the lack of knowledge and experience in navigating the South African regulatory environment, or more alarmingly, intentional disregard of it, can pose a risk to the safety of healthcare workers and patients, and lead to wasting limited resources.

The South African Medical Technology Industry Association (SAMED) is working with its 180 members and wants to support and guide other medical device suppliers to ensure that the provision of these products is done by companies that, if relevant, have been licensed by the SA Health Products Regulatory Agency (SAHPRA), and comply with the necessary safety, quality and efficacy standards.

“New hand gels, and different face masks and diagnostic tools are appearing on the market, and their composition, reliability and appropriate use differ. For example, it is not commonly known how much alcohol must be in a sanitiser or which type of PPE should be worn in which situation in order for it to be effective against this coronavirus. This can result in the use of sub-quality and inefficient products, inappropriate use of such items – and also cause harm,” says Avanthi Govender Bester, the Chairperson of SAMED.

SAMED collaborates with authorities, SAHPRA, the SA Bureau of Standards (SABS), the National Regulator for Compulsory Standards (NRCS) and other credible entities to assist local manufacturers and importers in following the regulations and is engaging with a range of stakeholders to find ways to ramp up local production of PPE and other related items.

“In addition to being a SAHPRA licensed establishment to legitimately supply most of these items, companies need to have in place processes for managing adverse events and recall of inefficient or unsafe products. In relation to screening and testing kits, respiratory aids and other more complex devices, the supplier also needs to be able to train healthcare providers on the correct use of equipment,” says Ms Govender Bester.

“The critical need for products related to the COVID-19 response has attracted companies which have little or no presence in the South African market. It can be difficult to distinguish *bona fide* suppliers from more opportunistic and unscrupulous suppliers. We appreciate collaboration with industry including SAMED so we can safeguard patients and medical personnel, and achieve optimal healthcare outcomes,” says Dr Boitumelo Semete-Makokotlela, the CEO of SAHPRA.

SAHPRA has established a dedicated hotline for medical devices, and has issued guidance documents, including those for rapid COVID-19 serological testing kits. Detailed information on the regulatory status of different products used in the prevention of the coronavirus infection was

issued jointly by SAHPRA, the NRCS and SABS. It encompasses face masks ranging from non-clinical cloth type to surgical (medical) and those that provide respiratory protection, general and medical gloves, and surface, hand and other body sanitisers and disinfectants.

In terms of face masks, the document indicates that:

- General face masks, when not intended for a medical purpose and no claim is made for protection from viruses, do not fall into SAHPRA's or NRCS' mandates.
- Surgical masks and medical masks are classified as Class A medical devices and are regulated by SAHPRA.
- Respirator and particle filtering half masks (dust masks) are classified as Class B medical devices must comply with specific requirements as guided by several different acts depending on their purpose and where they are being used – such as within medical or mining industry settings.

SAMED, with participation by SAHPRA representatives, will host a regulatory forum – a training webinar for members and all companies operating in or intending to enter the medical device sector. The forum will take place virtually from 10:00-12:00 on 12 May 2020 and anyone wishing to attend can email communication@samed.org.za.

"As part of our mission to advance innovation responsibly, SAMED has provided a guidance document to help companies manage the specific coronavirus demands within the confines of the Disaster Management Act – and without crossing the lines of ethical marketing and business practice. Requests from healthcare organisations or providers for urgent help with donations, rental of equipment or payment arrangements can be confusing, since these aspects of the customer-supplier relationship are carefully governed by the Medical Device Code.

"The COVID-19 epidemic has emphasised the role of medical technology in providing safe and effective care and enabling and protecting healthcare professionals and the public. SAMED is committed to working with members, and all medical device suppliers and stakeholders to strengthen South Africa's efforts to meet the demand for care and save lives," said Ms Govender Bester.

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About SAMED: The South African Medical Technology Industry Association (SAMED) is the voice of the South African medical technology industry. The association was formed in 1985 and aims to provide members with a collective, objective and credible platform to engage with stakeholders. SAMED's members include individual medical technology companies, associated members and associations.

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