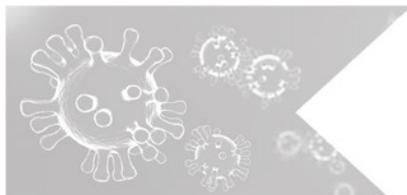


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## **SAMED COVID-19 NEWS** south african medical technology industry association

**COVID-19 news from SAMED, Government and Abroad.**

### **SAMED IN THE MEDIA - SA FM & NEWSROOM AFRICA INTERVIEWS**

SAMED issued a media statement about the need to ensure that medtech supplies and particularly essential products in the COVID-19 response are procured from licenced companies and are vetted for both quality and efficacy. Our spokespeople have had successful media engagements:

- SAFM: Avanthi Govender-Bester was interviewed on The Viewpoint by Songezo Mabece on 11/05/2020. [Click here](#) to listen.
- The SAFM write up can be found [here](#).
- Newsroom Afrika: Rob Millar was interviewed on Newsfeed AM by Mpho Sithole on 12/05/2020
- The media release was also added to the popular portals, Engineering News and Concrete Trends. [Click here](#) to read the Engineering News and [click here](#) to see it on Concrete Trends

The media coverage reflected SAMED's close and fruitful collaboration with the SA Health Products Regulatory Authority and supported the well-attended regulatory forum in which SAHPRA participated and which was attended by over 200 delegates from member companies, other medical suppliers and stakeholders.

The [SAMED Library](#) is a dedicated resource for all COVID-19 related updates, regulations, notices and news. All SAMED COVID-19 updates and related information can be found [here](#).

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### **DIRECTIONS REGARDING e-COMMERCE SALES DURING ALERT LEVEL 4 OF THE COVID-19 NATIONAL STATE OF DISASTER**

The Minister of Trade, Industry and Competition has issued Directions set out with regards to e-commerce sales during alert level 4. The purpose of these Directions is to provide direction on the goods which may be transacted through e-commerce platforms and the protocols which must be observed by retailer, couriers or delivery services and customers in respect of good transacted through e-commerce.

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Download the Directions [here](#).

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### **B4SA UPDATE: SPECIAL AMENDMENTS BUDGET GUIDELINES PUBLISHED BY NATIONAL TREASURY**

National Treasury today published guidelines for national government departments for a proposed Special Adjustment Budget which seeks to modify the 2020/21 national budget to redirect funding to provide for the rapidly changing economic conditions and enable spending on the COVID-19 response. A revised fiscal framework will also be presented, to account for substantial revenue losses emanating from the economic shock of the pandemic and subsequent lockdown.

The response package identifies broad areas of funding, which cuts across multiple programmes and departments. To ensure that funds are efficiently allocated, departments will be required to indicate resource requirements to respond to the COVID-19 pandemic. Such proposals must be aligned to the response package as announced by the President and presented by the Minister of Finance in the “Economic Measures for COVID-19” which was published on 30 April 2020.

**For more information about the guidelines and the timeline, go to [Special Amendment Budget Guidelines](#).**

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### **REQUEST FOR APPLICATIONS: DEVELOPMENT OF LOCAL DIAGNOSTICS AND REAGENTS FOR COVID-19**

The South African Medical Research Council (SAMRC) has announced a funding opportunity aimed at supporting the development of a local capacity to supply reagents for existing gold standard COVID-19 testing as well as to offer rapid alternatives for the direct detection of the virus.

The SAMRC invites researchers from recognised South African public universities, science councils and public research organisations, including the SAMRC’s intra and extramural units and collaborating centres, to apply.

The RFA is also open to not-for-profit and for-profit companies in South Africa who are involved in developing and manufacturing diagnostics and/or components. For more information and to download the relevant documents, [click here](#).

**Please direct queries or requests for information on this RFA to:**

Dr Michelle Mulder, Senior Program Manager: [michelle.mulder@mrc.ac.za](mailto:michelle.mulder@mrc.ac.za)

Application Closing Date: **29 May 2020**

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As different industry sectors resume operations in accordance with the different stages of the national lockdown, and employers begin to prepare the workplace to meet health and safety standards, hand sanitisers will once again be in high demand.

In order to provide corporate South Africa with a centralised source of approved and locally manufactured sanitisers, Proudly South African is compiling a page on its website where the sale of these products can be advertised.

At the same time as soliciting information from companies who wish to list on our portal, we will drive a consumer campaign directing individuals and companies to source their sanitiser from the portal, which will be non-transactional.

The page will provide the capacity and contact details of each listed manufacturer, and buyers will make direct contact with those companies that can assist with their specific requirements.

It is imperative that we leverage this opportunity for our own local manufacturers and that we provide South Africa with locally manufactured sanitiser.

**Qualifying companies wishing to register on the portal must:**

- (1) ensure that their products comply with the relevant legislation that regulates such products
- (2) register with Proudly SA, by sending an email to [info@proudlysa.co.za](mailto:info@proudlysa.co.za),
- (3) register on the portal by clicking on the link below.



For more information and to register as a vendor

[CLICK HERE TO REGISTER](#)

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### DO YOU HAVE A COVID-19 QUESTION OR QUERY?

Please visit the [FAQ Section](#) of our library as it provides answers to many of the frequently asked questions we receive.

#### What must I do to prepare my workplace and have staff return to work?

There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive [here](#)

You can also find useful tools on the [Return2Work website](#).

#### Where can I get a list of goods that are banned from export by the government?

The restrictions on Personal Protective Equipment are set out in the published [Export Regulations](#).

The regulation provides that items listed in schedules 1,2,3 and 4 shall not be exported from the Republic of South Africa except by virtue of an export permit issued in terms of Section 6 of the said International Trade Administration Act,2002.

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It is imperative to first read the notices as the regulatory is currently being inundated with calls and queries which are covered in these notices.

- [Specification criteria for COVID-19 serological test kits](#)
- [Joint Communication-Regulatory Status of Equipment Used to Help Prevent COVID-19](#)
- [NRCS media Release – Standards for Masks and Disinfectants](#)
- [Regulatory Requirements for the manufacture, distribution or wholesale of Serological COVID-19 Rapid Test Kits](#)
- [SAHPRA clarifies the issue of COVID-19 Rapid Test Kits](#)
- [Medical devices including IVDS requirement for supply in light of COVID-19 pandemic](#)

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## SAHPRA MEDICAL DEVICE CONTACTS

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.

- 084 220 8037
- 072 993 2273
- 078 281 6334

For queries on COVID-19 please email [mdcovid@sahpra.org.za](mailto:mdcovid@sahpra.org.za) and all other regular medical device queries can be sent to [MDnotifications@sahpra.org.za](mailto:MDnotifications@sahpra.org.za)

For general licensing queries: June Searela [june.searela@sahpra.org.za](mailto:june.searela@sahpra.org.za) / 072 828 2416

For COVID-19 related applications: Matlapeng Shabalala [Matlapeng.Shabalala@sahpra.org.za](mailto:Matlapeng.Shabalala@sahpra.org.za) / 071 302 0409 or

Khanyisile Nkuku [Khanyisile.Nkuku@sahpra.org.za](mailto:Khanyisile.Nkuku@sahpra.org.za) / 081 854 7109

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## PARTICIPATE ON BSA COVID-19 PORTAL

This effort is part of the broader SAMED collaboration with the Minister of Health via Business Unity South Africa's "Business for South Africa" initiative (BSA). During the current pandemic, up-to-date information is critical to ensure all key stakeholders in the value chain make the best-informed decisions at the right time.

The information collected on the [covid19manager.co.za](https://covid19manager.co.za) platform will be used to ensure supplier verification, regulatory compliance, product availability, reasonable pricing and providing the accurate and most up-to-date logistical information to the procurement department division at BSA to place orders from you and/or assist with ramping up local production. It is an automated process to help facilitate the overwhelming demand currently being experienced in South Africa during the weeks to come. The SAMED office, IDC, the dti, Minister of Health and the BSA procurement team will have access to the data. No data will be shared with other suppliers.

**NOTE: THIS IS A LIVE SYSTEM SO PLEASE UPDATE YOUR STOCK QUANTITIES AND LEAD TIME AS AND WHEN THEY CHANGE.**

Please see the following [link to the video](#) for an explanation of how to use the portal and click on <https://covid19manager.co.za/> to add your company and product information.

You will most likely be contacted by a member of the BSA procurement team should your information provided need to be verified or an order need to be placed. In this regard, we have put in place a security measure. The BSA procurement team will always supply you with your security code that only you have access to on the portal. See the video for reference as to where to find this code. Please never share or read this code to anyone but only have them read it back to you for validation. If at any point you feel your security code is compromised please let Tanya Vogt ([tanya@samed.org.za](mailto:tanya@samed.org.za)) know and it will be reset.

We are extremely appreciative of the support and commitment of our members in fighting this pandemic.

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## THE SOLIDARITY FUND

The Solidarity Fund provided more details on its purpose and mandate of mobilising and coordinating efforts and resources from all South Africans and the international community to assist most vulnerable South Africans to deal with the impact of Covid19 and the consequences of measures intended to slow its rate of infection. One of its key focus areas is a Health Response with direct support for the healthcare

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For more information email [info@solidarityfund.co.za](mailto:info@solidarityfund.co.za)

For offers of supply of Medicines and Medical Devices send to [covid19supplies@businessresponsecovid19.co.za](mailto:covid19supplies@businessresponsecovid19.co.za)  
If you are seeking PPE for your hospital, clinic, or NGO please email your request to [covid19requests@businessresponsecovid19.co.za](mailto:covid19requests@businessresponsecovid19.co.za)

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## COVID-19 EVENTS

### AHF-WHO COVID-19 DIALOGUE



WHO AFRICA & AFRICA HEALTHCARE FEDERATION



### A PUBLIC-PRIVATE DIALOGUE: HOW CAN WE WORK TOGETHER TO COMBAT COVID-19 IN AFRICA

SATURDAY, MAY 16, 2020  
4.00PM - 5.30PM (EAT)

REGISTRATION LINK: [HTTPS://BIT.LY/35ALPR9](https://bit.ly/35ALPR9)

#### SPEAKERS:

**Dr. Matshidiso Moeti**, WHO Regional Director for Africa  
**Mr. David Clarke**, WHO Leader UHC and Health Systems Law  
**Dr. Amit N. Thakker**, President Africa Healthcare Federation

[www.africaahf.com](http://www.africaahf.com)

@AfricaHealthFed

Africa Healthcare Federation

Registration Link: <https://bit.ly/35Alpr9>

#### CONDUCT A MEDICAL DEVICE RISK ASSESSMENT: ISO14971:2019

Join SGS for a FREE webinar that will provide an overview of the changes to ISO 14971:2019 and will help you to understand the relationship between risk management, regulatory requirements, and the quality management system.

**Date and time:** 19 May, 15:00  
**To register,** [click here](#).

#### SA CLINICAL TRIALS OVERVIEW DURING COVID-19

The keynote speaker, Professor Salim Abdool Karim will provide an overview of the current COVID-19 situation in South Africa, including updates and suggestions for tackling the pandemic.

**Date & Time:** 20 May 2020, 11:30 - 14:00  
**For more information,** [click here](#).  
**To register,** [click here](#).

#### EKA SNAP SESSIONS: COVID-19 & MEDICAL SCHEMES and COVID-19 & PRIVACY

Due to the success of the session on TERS/UIF, Elsabe Klinck and Associates has scheduled two more evening snap sessions.

- **COVID-19 & medical schemes** - what must be funded, how, scheme conditions on patient risk (e.g. not funding if high risk, requirements to telehealth, etc.) **20 May** 18:00; and
- **COVID-19 & privacy** is a major issue due to the issues with lists that must be kept as part of the Annexure E plan, screening systems, mandatory reporting of PUI & contacts, etc. **28 May**

Download the form [here](#).

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## COVID-19 DEVELOPMENTS

#### TRACKING THE PANDEMIC

<https://www.covid19sa.org/>

- South Africa has 12 074 coronavirus infections with the latest daily increase of 724 infections. The mortality rate is 1.81%, and so far, 219 deaths were recorded. Nearly 390 000 tests were conducted.

**ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL**

- Yesterday, President Cyril Ramaphosa announced the country will **drop to Level 3 of the nationwide lockdown by the end of May**, but some parts of the country with higher infection rates of COVID-19 will remain at Level 4. The National Coronavirus Command Council (NCCC) will begin a process of consultation on proposals for the implementation of the next level. Business activity under Level 4 will be expanded. Planned changes to Level 4 regulations include expansion of permitted business activities in the retail space and e-commerce, and reducing restrictions on exercise. The President said that the past seven weeks of lockdown has saved 1 752 lives - 35 people per day.
- The Auditor-General of South Africa (AGSA) is concerned the same problems persist year after year in the **national and provincial departments of health**. Some of the root causes are:
  - Inadequate oversight exercised regarding financial and performance reporting and compliance as well as related internal controls.
  - Lack of monitoring the implementation of action plans to address internal control deficiencies.
  - Inadequate implementation of proper record keeping in a timely manner to ensure that complete, relevant and accurate information is accessible and available to support financial and performance reporting.
  - No implementation of controls over daily and monthly processing and reconciling of transactions.
  - Lack of review and monitoring of compliance with applicable laws and regulations.
  - Inadequate consequences for poor performance and transgressions.
- [Demand for air travel](#) will lag behind pre-coronavirus forecasts for at least five more years, according to the latest projections from the International Air Transport Association. Traffic next year will be down between a third and two-fifths from projections made prior to the pandemic, according to IATA, which doesn't see travel recovering to last year's levels until 2023 at the earliest.
- [SA hairdressers](#) have taken the Health Minister Dr Zweli Mkhize to court demanding reopening of salons.

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SAMED is the voice of the South African medical technology industry. The not-for-gain 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, associate members and associations.

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