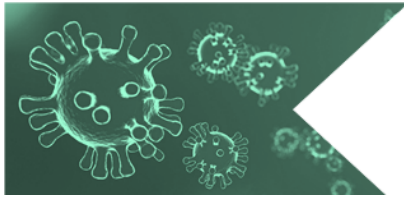


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SAMED COVID-19 NEWS south african medical technology industry association

COVID-19 news from SAMED, Government and Abroad.

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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](#).

SAMED ON COVID-19

PLEASE PARTICIPATE: COVID-19 products and company information portal.

We are aware of the constant requests by many sources for different information in different formats re COVID-19. SAMED being one of the 'asker's'. And that this is frustrating and time-consuming.

SAMED has worked hard over the last few days to create a live, online, safe and secure portal where the industry can submit their information regarding COVID-19 required products. (Note our previous excel sheets are no longer required). 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 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 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. SAMED will report to the Minister on the aggregated data.

We are aware that it is extremely difficult for you to secure overseas supply without a confirmed order, however, please be assured that all the products on the portal will be in high demand over the next while. We cannot say exactly how much and so ask your patience in this regard. We will

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understand that you may have existing orders in the pipeline promised for other customers, however, we urge you to consider diverting as much as you can now and going forward to this portal. If we unite and work together we can make a difference.

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) know and it will reset.

We are extremely appreciative of the support and commitment of our members in fighting this pandemic. [Back to top](#)

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.

QUESTION: Who do I contact at ITAC to assist me with my exports application?

ANSWER: ITAC import or export permit applications for disaster relief as a result of COVID-19 must be submitted electronically. Exemptions for exports all need to be directed to Marius Collins and Lufuno with the correspondence copied to Mohamed Vawda on all ITAC related issues.

- Marius Collins mcollins@itac.org.za
- Lufuno Maliaga lmaliaga@itag.org.za
- Mohamed Vawda MVawda@economic.gov.za.

You will need to complete the following documents:

- [IE361 Application or export permit: General Goods](#)
- [IE230 Application to register as an exporter or change of current information](#)
- [Questionnaire for Export Permit for COVID controlled Goods](#)

More details can be found on the [ITAC Communication to Stakeholders](#).

COVID-19 UPDATES, NOTICES, LEGISLATION AND REGULATIONS

COVID-19 export permit SOP

When you make your email submission, please include Export Permit Application in the subject line.

- For first time applications for export, applicants to complete [form IE230b](#) and the SARS tax certificate must be submitted.
- The [IE361 application form](#) for the export permit must be fully completed. Please make sure all details are shared and for a medicine application ensure that the INN stem is used together with the trade name and the SA SAHPRA product registration number.
- The [export permit questionnaire](#) must also be completed; please indicate on the form if not applicable.
- Email applications to Marius Collins mcollins@itac.org.za and Lufuno Maliaga lmaliaga@itag.org.za

Please ensure that applications forms are fully completed, the measure of quantity must be in accordance with the tariff heading, for example, medicines of tariff heading 30.04 is measured in kilograms (KG). If forms are not fully completed the application will be incomplete and may be delayed due to insufficient

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fixed quantities and fixed orders these should be added.

Download the SOP [here](#).

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Request by the DTI on operational issues faced by the medical devices sector

Continuing with the request from the dtic for a daily report on issues impacting the MedTech Industry, please let us know any NEW challenges. To support a collated response please use the below table format and send back to communication@samed.org. This is an ongoing initiative, please keep adding new matters as they arise.

Company name	Contact person	Email	Phone number	Summary of the issues impacting on the operations

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SAHPRA specification criteria for COVID-19 serological test kits

Initial specifications for serological test kits have been published by the Medicines and Healthcare products Regulatory Authority (MHRA) based on current information. SAHPRA has adopted the MHRA specification criteria for serology/antibody point of care test (POCT) only. This is a specification of the minimally (and some preferred options) clinically acceptable specifications for POCT tests to be made and/or used in South Africa during the current COVID-19 pandemic caused by SARS-CoV-2 virus. It sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the South African IVD industry, healthcare professionals and medical device regulators given the emergency situation.

Download the specifications [here](#).

SAMED is in the process of obtaining clarity on the approval and validation process. As soon as we have more information, it will be circulated.

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SAHPRA Medical Device Hotline

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



SAHPRA COVID-19 Medical Device Hotline

Commencing on Tuesday 14 April 2020,
The SAHPRA Medical Device Hotline will be active. Direct all COVID-Related queries relating to Medical Devices to the following Hotline numbers.

084 220 8037

072 993 2273

078 281 6334

Hours of Operation: (Excluding weekends and public holidays)

08:00 – 16:00



Download this notice, [here](#).

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DHL is still offering charters from Europe and China

DHL continues to successfully support the SAMED community, especially during the very challenging and extended COVID-19 lockdown period. They are still operating charters from Europe and China, as well as other regions.

For more information contact Mike Wood on 082 939 1768 or m.wood@dhl.com.

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BSA update

PPE DONATIONS - NEW SUPPLIER PORTAL

A dedicated supplier portal has been developed to streamline the PPE procurement process, and to ensure a quicker response to suppliers.

This will replace the previous email process.

<https://covid19manager.co.za/>

Live from Thursday, 16 April 2020



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The Solidarity Fund uniting South Africa against COVID-19

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

For offers of supply of Medicines and Medical Devices send

to covid19supplies@businessresponsecovid19.co.za

If you are seeking PPE for your hospital, clinic, or NGO please email your request

to covid19requests@businessresponsecovid19.co.za

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COVID-19 EVENTS

Free Webinar: BEE ownership for small and medium-sized businesses

From 09:00- 11:00 on Friday 24 April, Transcend will host a free webinar on BEE ownership. They understand that right now your energy and focus is on surviving and protecting your business and its employees. At the same time, it remains important to consider how to structure your business to remain competitive and grow in a post-lockdown South Africa. A strong BEE scorecard will be important and this might include Black ownership in your business.

This free webinar will set out Transcend Capital's simplified and cost-effective BEE ownership options for small and medium-sized businesses.

[Click here](#) to register or email Werner Mennen on werner.mennen@transcendcapital.co.za for more information

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Snap Session on COVID & Corporate Governance

At 10:00 on Friday 24 April 2020, Elsabe Klink & Associates will host a session, presented by Mike Judin of Judin Combrinck attorneys on COVID and corporate governance. There will be no charge for this session. Board members, compliance officers, regulatory- and legal heads, and those in company leadership teams are encouraged to participate. It will also be relevant to all entities structured as NPC's and all voluntary associations taking corporate governance seriously.

RSVP to eugenia@elsabeklinckassociates.co.za by Thursday 12:00.

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COVID-19 PRODUCT REQUESTS

South African distributor wanted: Ventilator supply for COVID 19

RespiratorsNZ is a New Zealand company which manufactures a Ventilator specifically for the COVID-19 response. Their product has been designed and manufactured to a RMVS001 Standard which is a NZ, Austria and UK standard specifically for rapid manufacture of Ventilators to assist save lives. They are looking to supply not only South Africa but all of Africa.

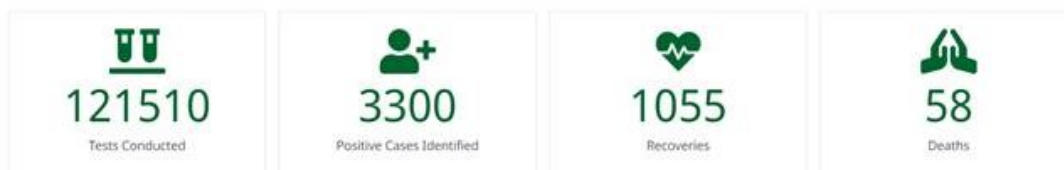
If you are interested in acting as a distributor for them, contact Georg Myburgh on +64 221 058 035 or support@respiratornz.co.nz. [Visit their website](#) for more information.

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COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

The latest figures released by the Department of Health (Monday 20 April) show:



Note from the Minister of Health: "Testing is the only way we can flatten the curve: We must know every individual that has been exposed, they must be immediately screened and those that require testing, must be tested without any delay while they remain in self - quarantine.

"If those contacts test positive, we must further identify their contacts because they also become potential positive cases. Simply put, this is a vicious cycle! And without quickly fully identifying confirmed cases and their direct contacts, the spread of the virus will just keep rising. This calls for us to take stringent measures to ensure that we have all the information that is required."

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the imposition of a nationwide lockdown we entered uncharted waters. South Africa has never had to deal with a public health emergency of this magnitude. "We had to act quickly to save lives. And we must acknowledge that, in the days and weeks that have followed, the provision of support to our country's most vulnerable citizens has been slower than required, and that lapses have occurred."

Ramaphosa said, in enforcing the lockdown, they had to consider the impact "on an already floundering economy in both the long and short term, and the impact of this substantial disruption on the livelihoods of millions of people". He said Cabinet will finalise a set of measures to respond to the impact of the lockdown on the livelihoods of South Africans.

This has been preceded by a range of engagements with a number of stakeholders, including business, labour, religious organisations, civil society and the Presidential Economic Advisory Council, he said (News24).

THE INTERNATIONAL PICTURE

USA

United States has the most fatalities in the pandemic:

- death toll has climbed by 1 433 in the past 24 hours to reach **42 094** (Johns Hopkins University)
- **784 000** confirmed cases

American President Donald Trump said on Monday that he planned to temporarily suspend immigration to the United States because of the pandemic. He said he will also move to protect Americans' jobs, though the pandemic crisis has already left 22 million people in the US out of work.

UK

A further 596 people have died with the virus, the lowest daily death toll in a fortnight, which follows a pattern of figures which suggest the UK could be nearing the peak of infections.

However, Prime Minister Boris Johnson has advised that the lockdown could remain in place for several months due to fears that Britain will suffer a deadly second peak of infections.

CLINICAL, SCIENCE AND NEWS ON THE SOCIAL ASPECTS OF THE PANDEMIC

Health minister Zweli Mhize has published new regulations that give the government [sweeping powers to redeploy doctors, nurses](#) and other health-care personnel to combat SA's Covid-19 epidemic.

This means that health authorities such as provincial health departments will be able to move personnel from one facility to another, to quarantine sites, to another town, or even across provincial boundaries.

Gauteng hospitals

Gauteng hospitals are gearing up for an increase in Covid-19 patients - measures include creating extra capacity of more than 550 beds and more than 300 intensive care units at public hospitals, with more bed space on the cards.

Private hospitals in the province are also expanding their resources, some spending hundreds of millions of rands on essential equipment. The Gauteng Provincial Command Council, a government body set up to respond to the Covid-19 crisis, said "we have created a capacity of 555 standard beds and 308 intensive care unit (ICU) beds".

Nine final days of lockdown extension

Experts say that the nine final days of the lockdown extension will be crucial as the country grapples with the spread of the novel coronavirus while attempting to resuscitate an ailing economy. Here are five things experts say the government must get a handle on:

1. **Community transmissions**
2. **A social-economic relief strategy**
3. **Ramping up testing**
4. **A public education campaign**
5. **Workplace screening**

Universities

Student representative councils at the University of Johannesburg and the University of Witwatersrand have [explored their institutions for more discussions](#) before online classes begin in full swing. Some problems students are having is living in areas without electricity or poor network coverage. Many universities [began online learning on Monday](#).

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activity on roads.

Hunger crisis

Sunday Times reported there is a looming hunger crisis, including “one million domestic workers, nearly 900,000 waste-pickers, 3.5 million elderly and 12 million children”. There are dire predictions of “food riots” and “looting”. The much-vaunted food parcels are not reaching the target groups.

According to *City Press*, many ANC local councillors “allegedly divert the aid to themselves and their supporters, and, in some instances, sell them on”.

Economic impact

[Bidvest](#), one of the largest companies in South Africa, has forced 70,000 of its staff (the majority) who can't work during national lockdown to take leave. If they don't have enough annual leave days available, this will be unpaid.

The wine industry and producers are asking for further relaxation, such as exemptions for road exports that they be allowed to start bottling for exports. R200-million is the estimated weekly financial impact of lost wine exports for South African producers. Over a four-week period, that would be R800-million of lost foreign currency in trade inflows. They stress that exports have nothing to do with the local consumption market.”

Storytelling

Private higher education MANCOSA's School of Education has partnered with the Gcinamasiko Arts and Heritage Trust to get Gcina Mhlope, a world-renowned actress, playwright, storyteller and author, to keep children captivated with her iconic voice and knack of storytelling. She will keep children educationally entertained for 10 days during the COVID-19 lockdown with a daily five-minute online story.

Audio recordings of the storytelling series will be available free of charge on MANCOSA's website (www.mancosa.co.za) from 20 April to 1 May 2020. They will also be available on MANCOSA'S social media pages – Facebook, Twitter, Instagram and LinkedIn.

“Lockdown must not only be about schoolwork for children. They also need time to set their minds free to imagine, dream and indulge in creativity.”

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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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