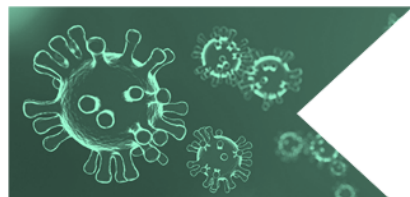


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## **SAMED COVID-19 NEWS** south african medical technology industry association

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

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### SAMED ON COVID-19

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](#).

#### **South African medtech industry streamlines health service's access to reliable, quality COVID-19 essentials**

In the weeks since the COVID-19 pandemic reached South African shores, the global race has been on to secure adequate supplies of personal protective equipment (PPE) for healthcare workers and essential equipment for treating individuals severely affected by the virus. While the focus has been on quantities of supplies, questions of quality and performance of products – and fair pricing – are equally important.

The South African Medical Technology Industry Association (SAMED) represents 180 companies that supply medical technology – such as emergency ventilators used in intensive care units and tests, PPE, devices and other essential medical products to the South African market.

As part of the Business South Africa (BSA) initiative – and with technical assistance from Tencent South Africa – SAMED has created a live online portal for its member companies to upload details of the COVID-19 supplies and equipment they are able to provide. [Read more](#)

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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](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 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 endeavour to keep you updated of the expected need as per attached example.**

We have the blessing from the Minister to procure locally first and via trusted credible suppliers. We 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](mailto: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.

### **Frequently Asked Questions (FAQs) relating to Essential Goods, clearance and movement of goods and service rendered by customs under the COVID-19 lockdown**

- What is the difference between critical supplies and essential goods?
- What do we need to know about the importation of critical supplies or essential goods to the national state of disaster (COVID-19 pandemic)?
- Do I need to apply for the VAT exemption under rebate item 412.11?
- Where can I find the certificate issued in terms of Schedule 1(8) of the Value Added Tax Act, 1991, item 412.11/00.00/01.00 (RE: SARS Essential Goods List)?

Find the answer to these and other questions [here](#).

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- Who are qualifying taxpayers?
- What are the requirements to claim the tax relief?
- What is the Employment Tax Incentive (ETI) tax relief?
- What is the Employees' Tax Deferral?

Find the answer to these and other questions [here](#).

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## **COVID-19 UPDATES, NOTICES, LEGISLATION AND REGULATIONS**

### **Presidential Speech 21 April 2020**

Many would have listened to the President's speech on the economic and social measures that will be taken in response to the COVID-19 pandemic. This includes an amount of R500 billion divided into various measures. The President indicated that a phased release of lockdown would be detailed on Thursday. **If you missed it, you can download the speech [here](#).**

"Even as we find ourselves at a moment of great peril, even as great sacrifices are demanded, even as we dare not allow our vigilance to waver, we look ahead to a better future. I have faith in the strength and resilience of ordinary South Africans, who have proven time and time again – throughout our history – that they can rise to the challenge." President Cyril Ramaphosa

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### **Risk-adjusted strategy for economic activity**

There is early evidence that the full national lockdown imposed since 26 March 2020 has successfully limited the spread of the coronavirus. However, there are serious risks associated with lifting lockdown restrictions too soon, or in an unsystematic and disorderly manner. Restrictions on economic activity need to be adapted to epidemiological trends, and may need to be relaxed and tightened in different periods. An alert system should be created with clearly defined levels of restriction that can be imposed by the National Command Council as necessary.

To determine which sectors should be allowed gradually to resume activity, three criteria should be used:

1. Risk of transmission (including the ease of implementing mitigation measures)
2. Expected impact on the sector of continued lockdown (including prior vulnerability)
3. Value of the sector to the economy (e.g. contribution to GDP, multiplier effects, export earnings)

A decision about whether to institute a lower alert level should be made by the National Command Council based on evidence gathered during this week about the spread of the virus.

**Download the strategy outline [here](#).**

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### **NRCS mask registration**

There are a number of NRCS documents required for registration of masks, relevant to masks manufactured and imported.

- [Sales permit application](#)
- [Filtering device COP & routine tests](#)
- [Application for approval of a respiratory protective device](#)
- [Technical file for respiratory protective devices](#)
- [Items required for the approval of respiratory protective devices](#)
- [Test Reports](#)
- [Application for the extension of the approval of a respiratory protective device](#)

**For more information contact:** [tando.magolego@nracs.org.za](mailto:tando.magolego@nracs.org.za) and [Thomas.madzivhe@nracs.org.za](mailto:Thomas.madzivhe@nracs.org.za)

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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

## SAHPRA Medical Device Hotline

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



The graphic is a white rounded rectangle with a blue border. At the top center is the SAHPRA logo, which consists of the letters 'SAHPRA' in a bold, blue, sans-serif font. Below the logo, the text 'South African Health Products Regulatory Authority' is written in a smaller, blue, sans-serif font. Below the logo and text, the title 'SAHPRA COVID-19 Medical Device Hotline' is centered in a bold, blue, sans-serif font. Underneath the title, the text '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.' is centered in a blue, sans-serif font. Below this text, three phone numbers are listed, each on a new line and centered: '084 220 8037', '072 993 2273', and '078 281 6334'. Below the phone numbers, the text 'Hours of Operation: (Excluding weekends and public holidays)' is centered in a blue, sans-serif font. Underneath this text, the hours '08:00 – 16:00' are centered in a blue, sans-serif font. At the bottom center of the graphic is a blue circular icon containing a white silhouette of a headset with a microphone.

Download this notice, [here](#).

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## Goods qualifying for import VAT exemption under item 412.11 – COVID-19 measures

SARS wishes to clarify that "essential goods" as defined in Regulation R.398 in *Government Gazette* No 43148 of 25 March 2020, other than the goods mentioned below, are exempt from VAT on importation under item 412.11/00.00/01.00 to Schedule 1 of the Value-Added Tax Act, 1991, read with section 13(3) of that Act.

Goods that are not exempt from VAT on importation are goods that the International Trade Administration Commission (ITAC) has indicated are:

1. dutiable (and no ITAC certificate under item 412.11 of Schedule No. 4 of the Customs and Excise Act, 1964, has been issued);
2. subject to the duties referred to in 1) but are entering South Africa duty-free because of a preferential trade agreement or other agreement, such as a customs union;
3. the subject of applications for duty support that are currently pending before ITAC; and
4. manufactured by domestic industry and ITAC has determined such industry is being or is likely to be injured by imports.

Goods excluded from the import VAT exemption under 1) are those goods that are subject to an ordinary customs duty, as set out in Schedule No. 1, or trade remedies (anti-dumping, countervailing or safeguard duty), as set out in Schedule No. 2 to the Customs and Excise Act, 1964. Goods excluded under 2) are also set out in these Schedules. A list of goods excluded under 3) and 4) is available in the relevant ITAC certificate. Click here for the [ITAC import VAT certificate](#) dated 30 March 2020. Click here for the [ITAC import VAT certificate](#) dated 8 April 2020.

Goods that qualify for VAT exemption and are not dutiable fall under the certificate issued by ITAC in this regard and no individual applications need be submitted to SARS or ITAC.

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importations from the BLNS, with measure 412.11/00.00/01.00.

During the COVID-19 pandemic, SARS Customs has also set up a command centre to deal with escalations that may have not been dealt with at branch level. Your existing call reference number, transaction (SSM/LRN) can then be sent to [osc@sars.gov.za](mailto:osc@sars.gov.za). To save duplication and time, clients are reminded that queries must be sent to the relevant branch/processing centre.

**Find out more** [here](#).

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### **Airfreight Capacity Available to Support the Pharma and Healthcare Sector**

As one of the freight forwarders who have a global focus on pharmaceutical and healthcare logistics, Kuehne+Nagel would like to be able to reassure companies that they are working tirelessly to provide airfreight capacity from Europe, USA and China .

**For more information** [click here](#) or contact Jacqui Bruan on 071 307 4570 or [jacqui.braun@kuehne-nagel.com](mailto:jacqui.braun@kuehne-nagel.com)

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### **BSA update: Proposal on tax changes to avoid long-term damage to SA economy**

Even before COVID-19, South Africa was under severe fiscal pressure. It is now accepted that the economic fallout resulting from the outbreak will inflict long-lasting damage to the local economy. Small businesses, in particular, are vulnerable and many will struggle to survive without support.

Given the urgency of the situation and the sheer scale and magnitude of the crisis, aggressive, decisive and immediate action through temporary and targeted measures is imperative to prevent (as far as possible) long term damage to the South African economy. In the medium term, more comprehensive policy-based interventions could be considered in order to boost economic growth (such as, for example, tax incentives and reduced tax rates). Business for SA has proposed several taxation interventions that South Africa should adopt urgently.

**To see the full proposal,** [click here](#).

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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 system, augmenting both the private and government healthcare sectors to ensure they have what they need, as well as enabling emergency supplies.

**Details on how to donate are available on the Fund's website** [www.solidarityfund.co.za](http://www.solidarityfund.co.za)

**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**

### **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](mailto:werner.mennen@transcendcapital.co.za) for more information

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### **Snap Session on COVID & Corporate Governance**

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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](mailto:eugenia@elsabeklinckassociates.co.za) by Thursday 12:00.**

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## **COVID-19 RELATED PRODUCT REQUESTS**

### **Request for COVID-19 products**

SAMED has received a request for infrared digital thermometer to test staff prior to them entering the pharma manufacturing facility. **If you are able to assist please contact James Meakings, Responsible Pharmacist, Azochem Laboratories Pty Ltd on [james.meakings@azochem.co.za](mailto:james.meakings@azochem.co.za)**

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### **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.

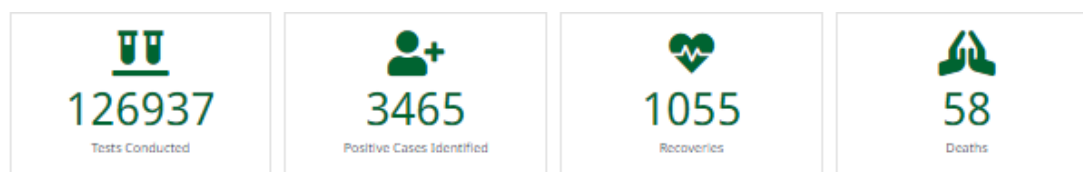
**If you are interested in acting as a distributor for them, contact Georg Myburgh on +64 221 058 035 or [support@respiratornz.co.nz](mailto:support@respiratornz.co.nz). [Visit their website](#) for more information.**

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## **COVID-19 DEVELOPMENTS**

### **TRACKING THE PANDEMIC**

The latest figures released by the Department of Health (Tuesday 21 April) show:



The number of confirmed COVID-19 cases has increased by 165, with no new reported fatalities. The country has now recorded 3 465 confirmed cases of the virus, with the death toll still at 58. The number of tests had increased, with 5 427 conducted in the last 24 hours. The number of tests conducted to date stands at 126 937. Gauteng remains the epicentre with 1 199 confirmed cases followed by the Western Cape with 1 010. Minister Zweli Mkhize, who was in the Eastern Cape on Tuesday, said the rapid rise of cases in the province was a concern.

### **RESPONSES TO THE PANDEMIC**

President Cyril Ramaphosa [announced](#) an R500 billion (about 10% of national GDP) social and economic support package to mitigate the impact of the coronavirus pandemic. It is the country's biggest one-time fiscal outlay and is almost ten times the amount spent in preparation for hosting the Soccer World Cup ten years ago, reported Fin24.

The support package includes the following major interventions:

- R200 billion loan scheme with major banks
- R50-billion boost for grant recipients
- R100 billion for jobs
- R70 billion in tax relief
- R20 billion for municipalities
- 250 000 food parcels
- Over R100 million to help protect frontline workers.

Some estimates have put the damage to the South African economy as a result of the COVID-19 lockdown at between 6 to 8%, with a million job losses expected. Details of phased reopening of the economy to be announced on Thursday – with a mention that infection hot-spots (Gauteng, Durban and Cape Town) may be prescribed more lockdown. Meanwhile, an additional 73 180 members of the SANDF have been deployed until 26 June 2020 to assist the police in managing the spread of COVID-19.

### **Travel and tourism**

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SAA seems not to be a priority for a government that is preoccupied with the economic fallout caused by the COVID-19 pandemic. The future ownership model of SAA remains unknown — whether the government will retain it as a national airline or cut ties with it by finding strategic equity partners. [Virgin Australia](#) is also reportedly battling to remain in business, and has been denied a bailout.

#### [Universities](#)

The University of Cape Town (UCT) is in the process of providing data to its students to allow for online learning. Wits University has announced that students will receive 30GB of data (10GB Anytime & 20GB at night) if they are registered with any of the country's four main networks – MTN, Vodacom, Cell C or Telkom. The university said that this service is at no cost to students and is valid for one month until 20 May.

#### THE INTERNATIONAL PICTURE

The United Nations is warning global hunger could double as a result of the pandemic, putting 250 000 million people at risk. About 2.5 million people around the world have been diagnosed with the coronavirus. More than 170 000 have died, with the US accounting for a quarter of all deaths, according to data compiled by John Hopkins University.

The United States has **826 240 infections**, and the most fatalities, with 3 279 deaths in the past 24 hours to reach **45 373**.

The mid-western state of Missouri has filed a civil lawsuit in a US court, accusing China of deception.

The true extent of Britain's COVID-19 death toll is more than 40 per cent higher than the government's daily figures indicated as of April 10, according to data. This puts the country on track to become among the worst-hit in Europe. UK has denied that not taking part in the EU medical equipment scheme was a "political decision".

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

- As the virus spreads, hospitals have been under the microscopic monitoring on how they are safeguarding their operations, especially after Netcare has had to shut two of its facilities (St Augustine's and Kingsway hospitals in Durban), while Parklands hospital, also in the same city, closed its emergency department over the weekend. Mediclinic closed new admissions at the Morningside hospital last week. Life Healthcare hospitals have designated wards for coronavirus patients; elective surgeries are now allowed and no patient visit are permitted.
- Researchers say they've developed a low-cost swab test that can [diagnose COVID-19 infections in about 45 minutes](#). The test is still to be approved by regulators.

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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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