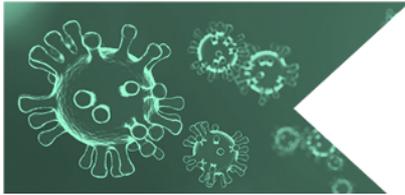


✉ Share this with those who need to know



## **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**

#### **SAMED compliance guidance document on emergency support during COVID-19**

This guidance document aims at supporting SAMED Member companies' legal and/or compliance teams when considering emergency processes to fast-track requests related to the COVID-19 crisis to the benefit to society while attempting to limit the inherent compliance risks.

**Note:** This Guidance document is not intended to supplant or supersede any national laws or regulations or professional codes, including company codes and companies' internal policies. The current situation is very fluid, and applicable laws change in a matter of hours through ordinances, decrees and other emergency legislative mechanisms.

Download the guidance document [here](#).

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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-SALDA Regulatory Forum: SAHPRA Licencing and amendments - A beginners guide**

**Programme:** *subject to change*

<b>09h45</b>	Log-on via Microsoft Teams link (please mute and turn off video when joining)
<b>10h00</b>	<b>Welcome</b> <i>Madeleine Pearce, SAMED Regulatory Committee Chairperson</i>
<b>10h05</b>	<b>Understanding the SAHPRA licencing Process</b> <i>Andrea Julsing-Keyter, Deputy Director Medical Devices, SAHPRA</i>
	<ul style="list-style-type: none"> <li>• SAHPRA licencing process – a step by step guide <ul style="list-style-type: none"> <li>• Forms to complete; Required documents; Cover letter; Important considerations; Who to contact/where to submit; Time frames</li> </ul> </li> <li>• SAHPRA licencing amendments <ul style="list-style-type: none"> <li>• When to submit a notice and when to apply for an amendment; Required documents; Important considerations; Who to contact/where to submit; Time frames</li> </ul> </li> <li>• SAHPRA licencing/amendment in light of COVID-19 – an expedited process <ul style="list-style-type: none"> <li>• Who should make use of this process; Who to contact/where to submit; Time frames</li> </ul> </li> <li>• COVID-19 Matters <ul style="list-style-type: none"> <li>• NRCS mask &amp; disinfectant requirements &amp; processes;</li> <li>• Serological test kits requirements and processes</li> </ul> </li> <li>• SAHPRA appeals process</li> </ul>
<b>11h05</b>	<b>Q &amp; A Session with the Regulator</b> <i>Sarah Cohen, Executive Officer, SALDA will facilitate questions with the regulator.</i> Please make use of the comment/chat stream to post questions
<b>12h00</b>	<b>End</b>

Click the link to Join

This will be a virtual meeting held via Microsoft Teams

Please only click the link at the above, specified date/time.

[Join Microsoft Teams Meeting](#)

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### PLEASE PARTICIPATE: BSA COVID-19 products and company information 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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### **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**

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- 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](#).

### Disaster Management Tax Relief FAQ's for Employees' Tax, ETI and Provisional Tax

- 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

### Amended Directions for the once-off movement of goods and persons

The Minister of Cooperative Governance and Traditional Affairs has issued and gazetted a set of amendments of the directions to address, prevent and combat the spread of COVID-19 in South Africa. These set of Directions are called the Directions on the once-off movement of persons and the transportation of goods for purposes of relocation. **The once-off movement will commence on 07 May 2020.**

The directions will allow individuals and business to move premises within, and across provincial, metropolitan or district boundaries during the period of Alert level 4. Citizens who were not able to do so due to the lockdown will be allowed to move houses with goods. This includes new lease agreements which were entered into before or during the lockdown period; or in instances where the property transfer occurred before the lockdown period. These directions are limited to a change in place of residence, including the transport of goods to a new place of residence, within the Republic.

Anyone who wishes to take advantage of this period to move, with their goods within, or across provincial, metropolitan or district boundaries, must obtain a permit from the station commander of a police station or a person designated by him or her. All removals must be performed in compliance with the COVID-19 regulations and the relevant Directions issued by the Minister of Transport.

Download the notice [here](#).

Download the amended Directions on the movement of goods [here](#).

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### National Treasury Loan Scheme for SMEs

As announced by the President, National Treasury, the South African Reserve Bank and commercial banks have jointly created a guaranteed loan scheme. The purpose of this scheme is to help small and medium-sized businesses and the economy. In terms of this scheme, R200 billion will be ultimately made available for new loans to existing customers. The initial phase will be R100 billion. The key features of the COVID-19 loan guarantee scheme are:

- COVID-19 loans will be available from banks to eligible businesses in good standing with their commercial banks with an annual turnover of less than R300 million.
- Funds borrowed through this scheme can be used for operational expenses such as salaries, rent and lease agreements, contracts with suppliers, etc. Loans will cover up to three months of operational costs and will be drawn down monthly.
- Banks are not obliged to extend COVID-19 loans, and those that do will use their normal risk evaluation and credit-application processes. A business' owners may be required to sign surety for the loan.
- Each business may accept only one COVID-19 loan.
- COVID-19 loans will be offered at a single, agreed lending rate by all banks participating in the scheme. The rate will track the repo rate.

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months to do so. Borrowers can repay the loan ahead of schedule.

- The scheme will be rolled out by banks over the next few weeks.

**Please contact your bank for further details and eligibility criteria.**

**Download the notice [here](#).**

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### NRCS Electrotech Performance and LOA Process

NRCS's Electrotech department has been hampered in delivering services. The lockdown has affected the revenue of NRCS and for the most part, the division has had very limited operations during the lockdown. They have been giving applications through to inspectors for review (however, this has been slower as all accompanying documentation has to be viewed digitally), however, administrators have not been working. The administrators are capturing all applications as they are able to receive them from inspectors. The final return of applications will be completed once they return to the office.

NRCS and SABS share office space and are working together to prepare the workspace to resume operations and ensuring that the regulated protocols are adhered to and taken into consideration. This will, hopefully, take place in the next week or two. The inspectors and administrators will likely continue to work from home and will come into the offices once a week to deliver applications they have processed and then collect the next batch of applications to process.

Applications which expire during the lockdown will be granted a temporary extension of validity until the conclusion of lockdown as long as the renewal application is submitted online.

**Download the Performance presentation [here](#).**

**Download the NRCS LOA process [here](#).**

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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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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](#)

Just another reminder that 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)

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### B4SA Update: Charter air freight opportunities

Business for South Africa's (B4SA) Medicines continues to be in contact with air freight operators and currently has details for 10 operators offering air freight availability into the country, primarily from Europe, China and India, and would be able to share details with interested parties. If you would like further details please reach out to Nicola Brink ([nicola@selfcareassociation.co.za](mailto:nicola@selfcareassociation.co.za)).

Download the BSA Response Update [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 PRODUCT REQUESTS

### URGENT: Request for manufacturers of body bags

Please note that there is a shortage of body bags for the COVID-19 response. Members who are able to manufacture body bags to kindly **contact Thandiwe Magagula (MDMSA secretariat) as soon as possible on 060 885 5305 or [mdmsasecretariat@mdmsa.co.za](mailto:mdmsasecretariat@mdmsa.co.za).**

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## COVID-19 EVENTS

### BSA Risk Assessment Presentation

Business for SA has performed a comprehensive risk assessment of the significant strategic risks arising from the COVID-19 crisis. The risk assessment has gone beyond the conventional two-dimensional approach to depicting risk and has taken a four-dimensional view by including considerations of risk interconnectedness and velocity. This enables consideration of the contagion effect of risks and will assist to identify and highlight those risks which, when addressed, will have the greatest effect on mitigating the other risks. **To view the full document, [click here](#).**

Given the technical nature of the assessment set out in this report BSA would encourage the participation of the presentation sessions as per the slots below:

Tues, 05 May; 07:30 to 08:30am

Tues, 12 May; 07:30 to 08:30am

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Thurs, 07 May; 07:30 to 08:30am

Thurs, 14 May; 07:30 to 08:30am

To enrol for any of the above sessions please contact: Daniella de Gouveia: +27 66 307 0846 or [Daniella.de.Gouveia@businessresponsecovid19.co.za](mailto:Daniella.de.Gouveia@businessresponsecovid19.co.za)

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## COVID-19 DEVELOPMENTS

### TRACKING THE PANDEMIC



Almost 269,000 reported killed worldwide from the deadly disease with cases up to 3.8 million and 1.3 recovered. Cases in the US 1.25 million with 75,500 deaths. Russia's coronavirus cases, which now stand at over 177,000, have overtaken France and Germany to become the fifth-highest total in the world after a record daily rise. As Europe and the US loosen their lockdowns against the coronavirus, health experts are expressing growing dread over what they say is an all-but-certain second wave of deaths and infections that could force governments to clamp back down.

### ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- [Inter-provincial](#) travel grace period has ended. From 1 May to 7 May, those who found themselves in provinces outside their places of work when the lockdown commenced, were given a window of opportunity to return to those provinces, so as to gradually resume economic activities.
- The tobacco saga continues to rage on, with the government not releasing minutes to a meeting which ended in a decision to keep the selling of tobacco outlawed during the lockdown. South Africans can move house again, as long as the country does not go back up to Alert Level 5. This is according to new regulations which say people and their household effects may move around South Africa on a once-off basis – even across provincial lines. There are terms and conditions – including that any move must happen by 7 June.
- If schools reopen, there is a [great concern for elderly caregivers](#) possibly contracting coronavirus from school kids. Around 12% of households are headed by grandparents, says a 2016 report.

### CLINICAL & SCIENCE NEWS

- [Pfizer begins coronavirus vaccine tests on humans](#). The pharmaceutical said on Tuesday that they have begun delivering doses of their experimental coronavirus vaccines for initial human testing in the United States.
- More than 100 South African doctors who studied overseas are in limbo because the country's presiding medical board is allegedly preventing them from writing an exam that would allow them to practise in their home country.

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South Africa. Here is the link to the interview:  
<https://drive.google.com/file/d/178yyrxEcJFAKO4Y43ETINTogwQmmHLlj/view>

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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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