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COVID-19 news from SAMED, Government and Abroad.

### UPDATE ON TESTING REQUIREMENTS BY HOSPITAL GROUPS: 18 JUNE 2020

It has been over four weeks since hospital groups introduced more stringent COVID-19 protocols for representative access to their hospitals. In some cases (Netcare), this includes a requirement that all representatives entering theatres present a negative test result not older than 7 days.

As previously reported, SAMED has deliberated at length on the matter and has met with Netcare in order to discuss the requirements, offer alternative solutions and commit to further engagement.

As a result, SAMED and Masoom have developed and introduced a COVID-19 specific programme into CRICE at all levels (white, blue and green). The COVID-19 animations add to the existing CRICE info that already covers PPE and Aseptic techniques. This programme has already been communicated to the industry.

In addition, SAMED has reviewed the potential risk categorisation of medical representatives and technicians depending on which hospital department they visit. There are hospital departments in which medical representatives would present far less of a risk and only the normal hospital screening should apply. Consequently, SAMED has proposed that COVID -19 testing only be required for medical representatives and technical assistants working in the presence of patients in potentially high-risk areas.



Notwithstanding the above, Netcare has distributed an updated letter on 10 June 2020 which retains the requirements for a negative COVID-19 test, not older than 7 days, to be presented on the day of access to the hospital.

As stated before, SAMED supports any screening, controlled or reduced access to hospitals and the correct utilization of PPE/hand sanitization. However, SAMED members, and the industry as a whole, continue to question the protocol for representatives to provide a negative COVID-19 test result every 7 days for a number of reasons; particularly, that the testing environment is under significant pressure and that the use of these testing resources for this purpose is not appropriate.

We have consulted widely on this matter with NICD, NIOH, RSSA, specific surgical associations as well as legal experts and despite the fact that both the NICD and Advamed (international) protocols do not include company representatives testing as a requirement, the input which we receive is consistent. The private hospitals have every right to determine the specific conditions for entry into their hospitals as they ultimately have the responsibility for the safety of their patients and staff. It is thus up to each health establishment to decide on their medical surveillance protocols that they wish to use.

Whilst this is clearly not the feedback any of our SAMED companies wish to hear, given the additional cost and logistical considerations, we currently have no choice but to comply with the hospital protocol requirements in terms of testing until further notice.

SAMED will continue to engage with Netcare as well as other hospital groups to ensure that a mutually beneficial compromise is reached as soon as possible.

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it had been just over 100 days since the first case of coronavirus was identified in South Africa and acknowledged the disruption the pandemic had brought to the lives and livelihoods of millions.

He shared the positive news of a breakthrough treatment of COVID-19 (the drug dexamethasone) which is also manufactured in South Africa and of which there is an ample supply. The drug reduced deaths among patients on ventilation by a third in an international study.

Ramaphosa highlighted how South Africa, like many other countries, has been affected by the global shortage of coronavirus test kits and other materials. He stated that SA had become more targeted with testing; prioritising patients in hospitals, health care workers, vulnerable people like the elderly and hotspot areas. He indicated that government was using every avenue available to source the supplies needed and to increase our testing capacity and improve the turnaround time within the labs.

Following further discussions with industry representatives on stringent prevention protocols, and after advice from scientists and consultation with Premiers, Cabinet decided to further ease restrictions on certain other economic activities.

These activities include:

- Restaurants for 'sit-down' meals
- Accredited and licensed accommodation, with the exception of home-sharing accommodation like Airbnb.
- Conferences and meetings for business purposes and in line with restrictions on public gatherings.
- Cinemas and theatres, to be aligned to limitations on the gathering of people.
- Casinos.
- Personal care services, including hairdressers and beauty services
- Non-contact sports such as golf, tennis, cricket and others. Contact sports will be allowed only for training and modified activities with restricted use of facilities



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**Changes to Level 3 regulations**

**STAY SAFE**  
PROTECT SOUTH AFRICA

**The following activities WILL BE ALLOWED at Level 3 with strict health protocols in place**

 <p><b>Restaurants for sit-down meals, with limited capacity</b></p>	 <p><b>Personal care services, including hairdressers</b></p>	 <p><b>Conferences for work purposes</b></p>
 <p><b>Commercially licensed accommodation (but not home sharing services)</b></p>	 <p><b>Cinemas, theatres and casinos, with limited capacity</b></p>	 <p><b>Non-contact sports, including golf and tennis</b></p>

**The entire country remains at Level 3 to contain the spread of coronavirus**

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 0600 123 456  
 EMERGENCY NUMBER  
 0800 029 999  
 sacoronavirus.co.za

  
 REPUBLIC OF SOUTH AFRICA



In each instance, specific and stringent safety requirements have been agreed on and will need to be put in place before a business can re-open, and protocols will need to be strictly adhered to for businesses to remain open. Announcements will be made in due course to detail these measures and indicate the date from which these activities will be permitted.

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government's commitment to aiding those affected by it. Ramaphosa indicate that alcohol abuse played a role in the increase of abuse (as well as an increase in road accidents) and how we, as a society, need to draw the lessons from this lockdown and decide how we can protect our society from the abuse of alcohol.

Download the President's address [here](#).

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## SARS: PUBLICATION OF EXPLANATORY SUMMARY OF THE DISASTER MANAGEMENT TAX RELIEF ADMINISTRATION BILL

SARS has issued a notice that the Minister of Finance intends to introduce the Disaster Management Tax Relief Administration Bill, 2020, in the National Assembly on 24 June 2020.

The Bill provides for tax measures in order to assist with alleviating cash flow burdens on tax compliant micro and small to medium-sized businesses arising as a result of the COVID-19 pandemic and measures taken under the Disaster Management Act, 2002; to provide for the employees' tax treatment of donations to the Solidarity Fund; to provide for a change in the value-added tax category of vendors to effect monthly returns and refunds and to provide for matters connected therewith.

Download the notice [here](#).

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## SAHPRA PRESENTATION ON RAPIDLY DEVELOPED VENTILATORS

Last Friday SAMED held a virtual session with the regulator on their published position paper on Rapidly developed ventilators (available on the [SAHPRA website](#)). For those interested in procuring or manufacturing rapidly developed ventilators, it is important to understand the SAHPRA requirements.

You can download the slides presented by the regulator [here](#).

Alternatively, if you were not able to attend the session, you can download a recording [here](#).

Please note this link will expire and we encourage you to take advantage thereof while the link is still active.

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## BRIEFING ON UIF TERS BENEFITS AND INVITATION TO COMPLETE A QUESTIONNAIRE ON UIF TERS

### WEBCAST

Business for South Africa today hosted a webcast where members were invited to hear a presentation and discuss challenges faced in applying for and receiving benefits from the Temporary Employer/Employee Relief Scheme (TERS).

The presentation by Robert Legh and Natalie Singer to the more than 100 participants was followed by a lively and detailed discussion. **The presentation can be found [here](#).**

### REMINDER: QUESTIONNAIRE ON UIF TERS

In an attempt to determine the scope of unpaid claims and current challenges B4SA has designed a quick questionnaire. They would like to ask for your urgent participation as the information gleaned will assist in their engagements with UIF officials.

Please note that the best person to complete this will be the individual who completed your business's online application.

Also, they request that you complete a questionnaire per UIF reference number as this questionnaire will double-up as a register of the Issues/Complaints and which will be sent to the UIF team.

## BUSINESS FOR SOUTH AFRICA WELCOMES REOPENING OF THE ECONOMY; JOINS PRESIDENT IN CONDEMNING VIOLENCE AGAINST WOMEN AND CHILDREN BRIEFING ON UIF TERS BENEFITS AND INVITATION TO COMPLETE A QUESTIONNAIRE ON UIF TERS

Business for South Africa welcomes President Ramaphosa's announcement last night (Wednesday 17 June) of the enhanced level 3 regulations which will further lift restrictions on many economic activities. They further wholeheartedly endorse the President's condemnation of violence against women and children and support his call for an end to femicide. B4SA calls on business and all of civil society to join the national campaign to support the victims and combat this scourge of our society.



Business has supported the lockdown because it dramatically reduced the speed at which the virus spread, allowing us time to increase capacity in our healthcare systems so South Africa can better deal with the coming surge of infections. They acknowledge the negative impact on lives and livelihoods from these restrictions.

The move to these enhanced level 3 regulations will allow more businesses to open, more people to work, and more services to be delivered to the public. Increased economic activity will heighten the risk of transmission and they repeat our call for each person in every workplace or social gathering to adhere to the health and hygiene protocols. We must all change our behaviour to protect not only ourselves, but our families, colleagues, friends, and communities. We are responsible for protecting them.

As business, B4SA continues to call for evidence-based interventions that balance health, economic recovery, and societal impact.

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## VIRTUAL CONFERENCE: AFRICA'S LEADERSHIP ROLE IN COVID-19 VACCINE DEVELOPMENT AND ACCESS

Recognizing the urgent need for collaboration, cooperation, and coordination to ensure that Africa plays a leadership role in the development and access to potential vaccines, this two-day virtual conference, under the leadership of H.E. Moussa Faki Mahamat, Chairperson of the African Union Commission (AUC), will bring together healthcare professionals, researchers, public health experts, policymakers, media, civil society, community and religious leaders, and industries to explore this topic and help develop a framework for COVID-19 vaccine development and access in Africa.

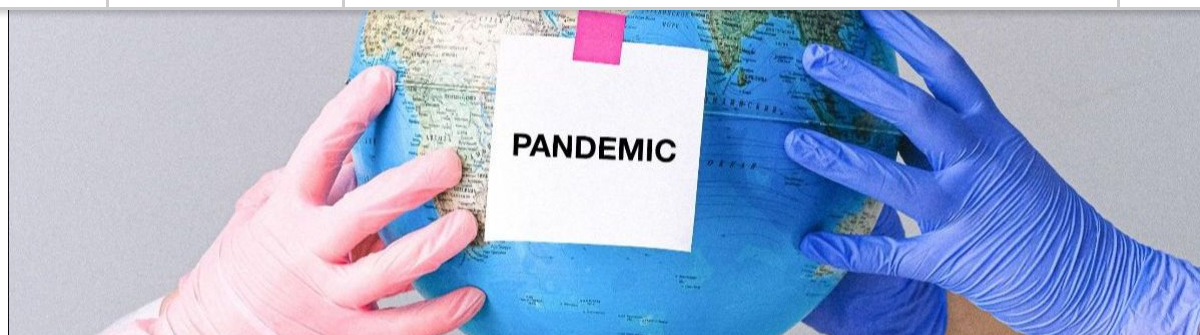
**When: 24 & 25 June 2020**

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

**To register, [click here](#).**

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## REPORT UNLICENCED COMPANIES TO SAHPRA

Several members have contact SAMED about companies trading medical technologies without a SAHPRA Medical Device Establishment License. These companies are trading illegally and it is essential that they be reported to SAHPRA for investigation.

SAHPRA has published a list of licenced companies under documents on their [medical devices page](#) which you can use to check if the company has a Medical Device Establishment License before sending a report. You can download this list as at 26 May 2020, [here](#). Please ensure that you visit the SAHPRA website to obtain updates as this is an evolving list.

Report unlicensed companies by emailing: [mokgadi.fafudi@sahpra.org.za](mailto:mokgadi.fafudi@sahpra.org.za)

## IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- [MD010 Guidance Rapidly developed ventilators 26May2020 v1](#)
- [PCR Tests Authorised for Listing by SAHPRA – 19.05.2020 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 IN-VITRO DIAGNOSTICS \(IVDS\) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE 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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resource for all COVID-19 related updates, regulations, notices and news.

All SAMED COVID-19 updates and related information can be found here.

CLICK HERE



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.



### PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA [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.

**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.

If you have any questions about the status of your registration, on the types of PPE and medical equipment that B4SA are procuring, if you are struggling to complete your application, or if you have any other queries, please get in touch with the B4SA support team via [covid19portal@businessresponsecovid19.co.za](mailto:covid19portal@businessresponsecovid19.co.za). If you are not receiving feedback from the administrators, please check your spam/junk folders.

SAMED is 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 system, augmenting both the private and government healthcare sectors to ensure they have what they

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

### OMMIA HEALTH COVID-19 VIRTUAL EXPO

Ommia Health Live are bringing together the global healthcare industry, for the largest virtual gathering ever seen before, a whole new concept planned from the ground up to be more diverse and accessible, **taking place 22-26 June 2020.**

[Join the experience here](#)

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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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