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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

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](#).

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 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

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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 be 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](#).

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](#).

COVID-19 UPDATES, NOTICES, LEGISLATION AND REGULATIONS

COVID-19: What one must do in level 4

The first salvo of inspections by the Department of Labour has taken place at workplaces, including health sector entities. The information below is all the requirements under the 29 April 2020 Alert Level 4 Regulations. To summarise what you need to do should you have staff (*even if just occasionally*) in the office, and/or if you are opening and/or are sending company representatives and/or healthcare professionals into the field:

1. For all **staff** that travel, the Annexure A, Form 2 **Permit to Travel** to render an essential and/or permitted service, is required. This permit must include the employee's home address and all the addresses to where s/he travels, as well. (Regulation 16(2)(b)).
2. The business must have a so-called **Annexure E Plan**, that includes:
 - 2.1 the issues prescribed in **regulation 5(3) to (7) and 16(6)** and Annexure E to the Regulations

and cloth face masks, etc.

3. Addressing considerations of **privacy/confidentiality** relating to the mandatory staff lists, and the implications of co-morbidity disclosures as well as the mandatory reporting of PUI and COVID-19 cases to the NICD (Regulation 6 to 8; Notifiable Diseases Regulations, 15 December 2017). It is proposed that these matters be drafted as a workplace policy and incorporated into the Annexure E plan.

4. For **patient-facing services**, companies should ensure that the **consent** forms in relation to such services are updated to address COVID-matters and that if patients have to **travel** to access the service, that some form of confirmation of appointment is provided to allow such travel - also note that travel during curfew can only take place by patients to access emergency care.

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PMG: COVID-19 State of Disaster & Lockdown Regulations Update 11 May 2020

Several ministerial directives issued under Covid-19 lockdown Level 5 have been amended or, in some cases, repealed and replaced. They should be read with the 29 April disaster management [regulations](#) on Lockdown Level 4. Some of those include:

Health

- The 1998 Medical Schemes Act regulations have been [amended](#) to provide for Covid-19 screening, clinically appropriate diagnostic tests, medication, medical management (including hospitalisation and the treatment of complications) and rehabilitation.
- Schedule 2, 3 and 4 substances prescribed for continuous therapy have been [excluded](#) from a requirement in terms of which, under normal circumstances, they may not be dispensed for longer than six months. This arrangement will remain in place for 18 months.

Temporary Employee/Employer Relief Scheme (TERS)

- According to a ministerial [directive](#) issued on 4 May:
 - employers with operations closed for up to three months during the Covid-19 lockdown 'must' apply on behalf of affected employees for benefits available under the scheme
 - TERS benefits are also available to UIF contributors who have been 'required to take annual leave' during the lockdown. In such instances, the employer may off-set the TERS benefit received 'against the amount paid to the employee in respect of annual leave' – subject to meeting certain conditions.

Tax

- The list of essential financial services has been expanded under Lockdown Level 4. According to a ministerial [directive](#) issued on 4 May:
 - the list now includes tax services conducted by an external service provider or directly by a taxpayer, trader or an employee of a taxpayer or trader in respect of the taxpayer's or trader's affairs, but
 - only when such services are required to comply with an obligation or to exercise a right afforded, in terms of a tax Act or the 1964 Customs & Excise Act.

Transport

- Four ministerial directives and two Government Gazette notices affecting transport operations have been repealed and replaced with new directives reflecting measures to be taken during Lockdown Level 4 at [seaports](#), by [railway](#) operators and by operators of all modes of [road](#) passenger transport services.
- Only mining-related air freight services are deemed 'essential' under Lockdown Level 4, according to a ministerial [directive](#) issued on 4 May, although flights necessary for aircraft maintenance purposes are also permitted.
- In another [directive](#):
 - the validity of expired motor vehicle licences and permits was extended, and
 - driving licence and vehicle testing centres were authorised to resume operations.

Download the summary of these and other changes [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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Make sure you have read these SAHPRA Medical Device notices

Just a reminder to download and read all the below notices. 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](#)

Just another reminder that queries on COVID-19 please email mdcovid@sahpra.org.za and all other regular medical device queries can be sent to MDnotifications@sahpra.org.za

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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
For more information email info@solidarityfund.co.za

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COVID-19 PRODUCT REQUESTS

Offer to supply plastic bottles

Members looking for plastic bottles for hand sanitisers, we have an offer from Brand Line to supply these to the market.

If you need bottles, please contact Johan Meiring directly on 082 903 8374 or johanm@brandline.com.

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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

Wed, 06 May; 07:30 to 08:30am

Wed, 13 May; 07:30 to 08:30am

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

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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.africahf.com

@AfricaHealthFed

Africa Healthcare Federation

Registration Link: <https://bit.ly/35ALpr9>[Back to top](#)

How to conduct a medical device risk assessment as per ISO14971:2019

Join SGS at 15:00 on 19 May 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.

Objectives:

- Understand the key elements required for the management of risk as specified in ISO 14971:2019 and changes from ISO 14971:2007

- What can SGS do to help?

This webinar is for current Medical Device companies and those that manufacture medical devices.

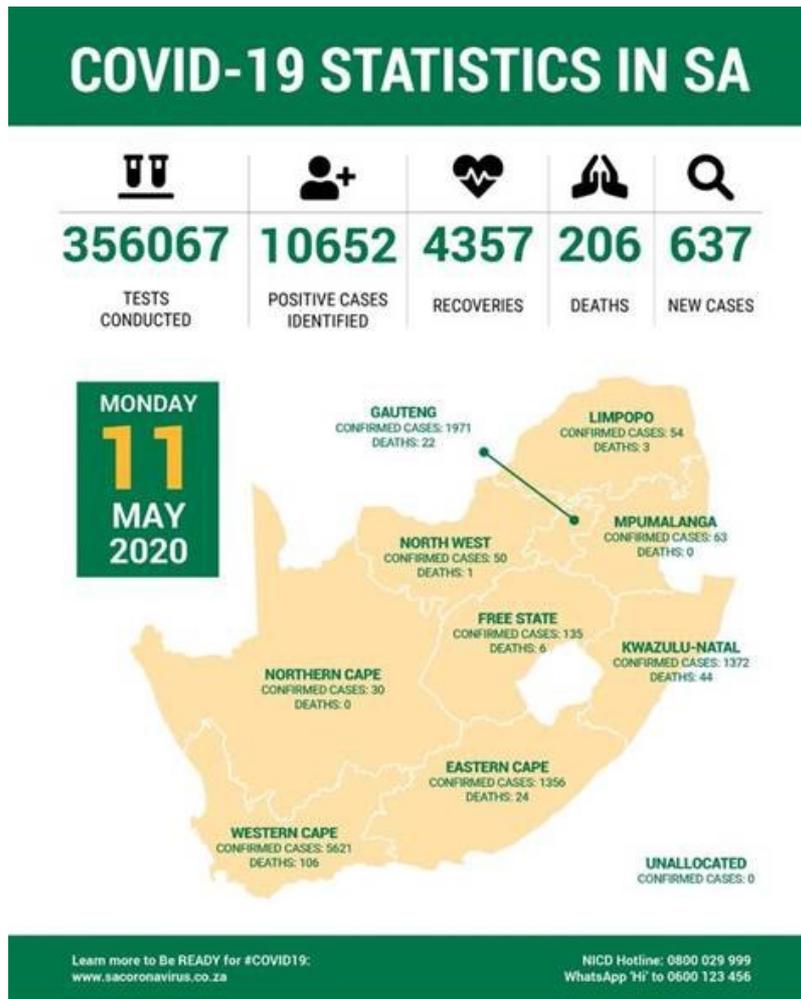
To register, [click here](#).

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COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC

The latest position is summarised in the graphic below. The daily number of new cases is increasing steadily under Level 4 lockdown conditions.



What does this mean

Please remember: the better the testing, the more “mild” cases are confirmed (instead of being missed) and the lower the death rate as a % of confirmed cases. This can PARTLY explain the situation below. But South Africa’s testing is NOT particularly exhaustive (although screening is quite widespread) so we are probably missing mild cases.

	Confirmed cases as % of tests	Recoveries as % of confirmed cases	Deaths as % of confirmed cases
South Africa	3%	40.9%	1.9%
US	-	15.9%	5.9%
UK	-	-	14.4%
Russia	-	18%	0.9%
Spain	-	60.4%	11.8%
Global	-	35%	6.8%

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- President Cyril Ramaphosa **cautioned** in his weekly letter that South Africa should be prepared to live with the Covid-19 epidemic for at least a year and called on people to make long-term changes in their behaviour. He said proceeding to the next level of lockdown would depend on an expansion of testing and contact tracing as well as improved capacity for sanitisation and infection-proofing of workplaces. (News 24)
- Police Minister Bheki Cele warned that more people were **flouting lockdown** regulations under level 4 than previously. He cited the number of infringements of the ban on transporting alcohol as evidence of this.
- Cosatu has urged an easing of the lockdown **“as soon as it is safe to do so”**. The organisation sees the urgent economic need for this but also warns that employers and transport systems need to do a lot more to secure the safety of workers. Without this, further opening of the economy would be tantamount to “throwing workers under the bus”. (Business Live and SAfm)

HEALTH DEVELOPMENTS

- UNAIDS and the WHO issued a joint statement warning that deaths due to HIV in sub-Saharan Africa could double due to the disruption of healthcare by the Covid-19 epidemic. It estimated that additional deaths could number 500 000. In 2018 the estimated number of deaths in the region was 470 000.
- For a think piece on the need for South Africa to improve its pharmaceutical and related manufacturing capacity go to: South Africa can't get enough Covid-19 testing supplies - here's why we should be making our own: [click here](#)

ECONOMIC IMPACTS

- The oil price, which rallied slightly last week on the back of economies beginning to open up, fell again yesterday, apparently in response to fears of a second wave of infections in countries that are currently recovering. (Bloomberg)
- Life Healthcare issued a notice to shareholders stating that the Covid-19 epidemic had begun to impact on its operations as early as February and this was reflected in interim results for the first quarter. Revenue still increased 6.8% to R13.2bn and earnings per share were up 12%. The company said its position was still strong but did not declare a dividend.

SOCIAL DEVELOPMENTS

- The Department of Social Development will be hiring and deploying some 1 800 additional social workers to provide psychosocial support to families during the lockdown. The Health and Welfare SETA and the professional council for social service workers will also be putting an additional 1 210 social work interns into the field. Regulations are being amended to allow for the release of children from care institutions and individuals from rehabilitation institutions on the recommendation of a social worker. Normally a more complex process would apply. (News 24 and Classic fm news)
- The national government's toll-free GBV hotline received 120 000 calls during the first three weeks of the lockdown, according to SACSoWach, a coalition of 33 NGOs. (News 24)

SCIENCE & RESEARCH

- A study conducted by researchers at Anglia Ruskin University and published in the journal Aging Clinical and Experimental has found a link between **vitamin D deficiency and higher rates of serious Covid-19 illness**. Vitamin D keeps white blood cells in check. If white blood cells get out of control they cause an overreaction of the immune system, triggering the observed “cytokine storm” which can lead to organ failure.
- A study published in the European Heart Journal has an explanation for the **higher susceptibility of men** to the coronavirus. It argues that an **enzyme, ACE2**, which is present in men and not in women provides sites for the spikes of the virus’ “corona” to bind to. Once bound, it can multiply and cause illness. The article assured men who are taking medication for heart failure that this does not increase their risk above the rest of the male population, (Health 24)

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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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