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COVID-19 news from SAMED, Government and Abroad.

TECHNICAL INFRASTRUCTURE INSTITUTIONS' CONTRIBUTIONS TO GOVERNMENT'S COVID-19 RESPONSE

The Portfolio Committee on Trade and Industry was briefed via a virtual meeting on the Technical Infrastructure Institutions' contribution to government's COVID-19 response. The Competitiveness and Growth Division of the Department of Trade, Industry and Competition, which led the delegation, noted that there was a huge demand for personal protective equipment (PPE) products and other products related to Covid-19.

- **The South African Bureau of Standards (SABS)** said a small laboratory complement had continued to work and was looking at assignments bought for the public health sector.
- **The National Regulator for Compulsory Standards (NRCS)** reported it had supported essential services in processing applications for detergents, masks, disinfectants, and measurements of the packaged goods, including personal protective equipment and automotive services to support essential services. The NRCS had re-engineered processes and issued temporary permits for masks. There had been no regulation for sanitisers so the NRCS had submitted a standard to the Minister.
- **The South African National Accreditation System (SANAS)** staff had been unable to go on-site and so had developed a remote assessment process that met international standards. A total of 12 laboratories, including the National Health Laboratory Service and private laboratories, had been identified to be accredited for COVID-19 testing. A working group was being established to provide guidance for the calibration of the infrared (IR) thermometers used for testing for a high fever. SANAS had accredited three laboratories to test sanitisers, disinfectants and soaps. A difficulty was that there was no accredited laboratory for testing masks.
- **The National Metrology Institute of South Africa (NMISA)** had been involved in the development of a sanitiser solution for taxis and was part of the national ventilator projector, providing accurate measurements to ensure that the ventilators would be safe.

Download the minutes of the meeting [here](#).

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COVID-19 RESPONSE UPDATE BY HEALTH MINISTRY/DEPARTMENT

The Portfolio Committee welcomed the Committee Report on the 2020/21 Health Budget. It is the duty of the Committee is to assist the Department of Health (DoH) and National Treasury to ensure that the revised budget is in alignment with the work that needs to be done to combat COVID-19 and strengthen the healthcare system.

Members from the Portfolio Committee gave feedback to the rest of the Committees on the recently conducted oversight site visits in the Western Cape and KwaZulu-Natal. Members noted the impressiveness of the Cape Town International Convention Centre (CTICC) as a field hospital that will be opened on 8 June 2020 with 862 beds available to receive patients on their road to recovery. Tygerberg Hospital is currently an operational facility that is experiencing shortages in staff, testing materials and kits, and Personal Protective Equipment (PPE) which must be addressed quickly. Members were concerned that even though hotspots in the area have been identified and hospitals are doing well, there are significant delays in the test results of individuals.

DoH updated the Committees on its response to COVID-19, which included outlining the global and national situation of the pandemic, the hotspots of the disease, the weekly averages of new confirmed cases, the divide between public and private sector testing, and other crucial statistical information. The biggest challenge with the pandemic is to flatten the curve to reduce the number of people that are infected at one time to enable the healthcare system not to be overburdened.

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NICD COVID-19 DISEASE: INFECTION PREVENTION AND CONTROL GUIDELINES

Updated 21 May 2020

This guideline provides guidance regarding infection prevention and control in health care facilities with specific reference to COVID-19. It should be read in conjunction with the National Infection Prevention and Control Strategic Framework and the Practical Manual for the Implementation of the National Infection Prevention and Control Strategic Framework.

Download the guidance document [here](#).

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BUSINESS FOR SA | COVID-19

5-STEP ROADMAP TO RE-OPENING YOUR BUSINESS

How to re-open your business safely and legally

Every employer will, during each of the levels of lockdown and for the foreseeable future, have to adhere to detailed occupational health and safety protocols. This means that all employers must re-examine their activities, work environment and policies in the light of the COVID-19 pandemic and may need to change, adapt or enhance these in order to operate.

The [Return to Work 5 Step Roadmap](#) provides valuable tools and guidelines to expedite a safe, effective and structured return to work plan.

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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](#).

[CLICK HERE](#)



NOTICE OF EXPIRATION OF REBATE CERTIFICATES

Rebate certificates issued by the International Trade Administration Commission of South Africa (ITAC) under rebate item 412.11 have expired effective midnight 31 May 2020. ITAC will not be issuing new



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

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 and all other regular medical device queries can be sent to MDnotifications@sahpra.org.za

For general licensing queries: June Searela june.searela@sahpra.org.za / 072 828 2416

For COVID-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or

Khanyisile Nkuku Khanyisile.Nkuku@sahpra.org.za / 081 854 7109

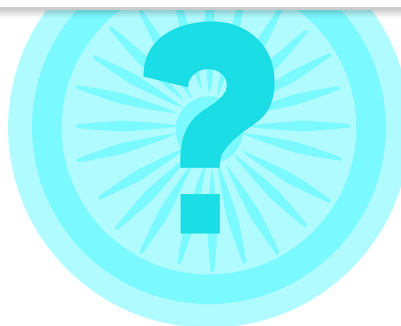
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DO YOU HAVE A
COVID-19
QUESTION OR
QUERY?

Please visit the [FAQ](#)

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answers to many of the frequently asked questions we receive.



What must I do to prepare my workplace and have staff return to work?

There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive [here](#)

You can also find useful tools on the [Return2Work website](#).

PARTICIPATE ON B4SA COVID-19 PROCUREMENT PORTAL

The information collected on the B4SA 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. 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 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

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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PTCMA WEBINAR: INSIGHTS DURING COVID-19

Measuring the impact of COVID-19 on our healthcare environment - what about our economy?

- Where is the Ministerial Advisory Committee (MAC) coming from?
- A vaccine needs to be developed sooner rather than later for COVID-19 but what happens in between?
- Where do we stand with the treatment development for COVID-19?

Date: 5 June 2020, 09:45 - 12:30

For more information or to register, [click here](#).

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OMMIA HEALTH COVID-19 VIRTUAL EXPO

Omnia 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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