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


## **SAMED MEMBER FORM WITH SAHPRA ON RAPIDLY DEVELOPED VENTILATORS**

Join SAMED on a call with SAHPRA on the publication of Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for COVID-19.

Download this important communication from the [SAHPRA website](#).

**Regulatory Member Forum:  
SAHPRA on Rapidly Developed Ventilators**

**12 June 2020**

  
**SAMED**  
south african medical technology industry association  
advancing innovation responsibly

In response to the anticipated shortage of medical supplies and equipment in the health care system as a result of the outbreak of the COVID-19 pandemic, the South African Health Products Regulatory Authority (SAHPRA) has drafted minimum requirements for the manufacture, importation and distribution of rapidly developed invasive and non-invasive ventilators. SAHPRA has added this new guidance on the rapidly developed ventilators to their [website](#).

It covers the regulatory requirements, technical specifications, licence conditions and authorisation for use of unregistered rapidly developed invasive and non-invasive ventilators for COVID-19.

The Regulator will present this position paper and address questions and concerns from the membership.

**Programme:** *subject to change*

|       |   |
|-------|---|
| 09:00 | <b>Opening</b><br>Madeleine Pearce – SAMED Regulatory Committee Chairperson   |
| 09:10 | <b>SAHPRA on Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19</b><br>Momeena Omarjee – Inspectorate and Regulatory Compliance, SAHPRA |
| 10:30 | <b>Close</b>  |

This will be a virtual meeting held via Microsoft Teams

**Please use the link provided to  
attend at the specified date/time**

[Join Microsoft Teams Meeting](#)

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## **NVP (NATIONAL VENTILATOR PROJECT) STREAM 2**

This is a Request for Information (RFI) to identify role players to assist the South African Radio Astronomy Observatory (SARAO), who has been mandated by the Minister of Trade, Industry and Competition to manage the process in the National Ventilator Project (NVP) Stream 2. The RFI follows on an earlier Call for proposals (CFP) for CPAP ventilators, which was published in April. The objective of this call was to meet the anticipated demand for simple, low-cost ventilators that can be rapidly produced, certified and deployed in large numbers, in order to treat the majority of hospitalised COVID-19 patients.

This is at an advanced stage of development and this RFI is designed to be complementary thereto. The objective of the Stream 2 Project is to establish a support or incubation program to meet the anticipated ventilator demand for the treatment of a smaller number of critically ill patients. The Minister of Trade, Industry and Competition, therefore, invites submissions to be made to SARAO relating to the design, development, certification and production of ventilators and supporting

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advanced than the ventilators produced in first call, namely:

- Bi-level Positive Airway Pressure (BPAP) non-invasive Ventilator System (BVS), and
- Invasive Ventilator System (IVS)

Due to the more advanced nature of these devices and the likely inclusion of electronic control, it is expected that certification will be more challenging than for STREAM 1 devices.

Download the Request for Information [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](#).**

**CLICK HERE**



## 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.

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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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### 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.



### 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](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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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

### 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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## COVID-19 DEVELOPMENTS

### TRACKING THE PANDEMIC

|                  |  |                        |  |                        |  |                        |  |                  |  |
|------------------|--|------------------------|--|------------------------|--|------------------------|--|------------------|--|
| Cumulative Cases |  | Daily change           |  | Cumulative Fatalities  |  | Mortality Rate         |  | Total Recoveries |  |
| 52,991           |  | +2,112                 |  | 1,162                  |  | 2.19%                  |  | 29,006           |  |
| Active Cases     |  | Relative to Population |  | Relative to Population |  | Relative to Population |  | Total Tests      |  |
| 22,823           |  | 0.0902%                |  | 0.001977%              |  | 0.001977%              |  | 968,070          |  |

| Gauteng        | Western Cape | KwaZulu Natal | Free State | Eastern Cape | Limpopo | Mpumalanga | North West | Northern Cape |
|----------------|--------------|---------------|------------|--------------|---------|------------|------------|---------------|
| 6,546          | 34,819       | 3,255         | 391        | 6,760        | 253     | 184        | 604        | 122           |
| Daily Increase |              |               |            |              |         |            |            |               |
| 288            | 1,251        | 80            | 18         | 419          | 9       | 1          | 24         | 4             |

The World Health Organisation said this week that the coronavirus [pandemic situation was worsening around the globe](#), as it warned against complacency. The WHO said it had recorded its highest daily tally of new infections, with COVID-19 raging in the Americas. WHO chief Tedros Adhanom Ghebreyesus said more than 100 000 cases have been reported on nine of the past 10 days. He said that almost 75% of cases recorded on 7 June came from 10 countries - mostly in the Americas and South Asia.

The WHO also issued a guide (see graphic below) on how to correctly use non-medical/cloth masks.





## ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

- New COVID-19 labour-related regulations make it possible for [employees who have been diagnosed with the virus to return to work without testing negative for the virus](#). This is one of the amendments Labour and Employment Minister Thulas Nxesi has made to alleviate pressure on laboratories. According to the new directives, an employee who contracted the virus can return to work after spending 14 days in quarantine provided a medical evaluation confirms they are fit for work.
- Minister of Higher Education, Science and Innovation Dr Blade Nzimande addressed the media in Pretoria yesterday (9 June) on [the state of readiness for the phased return of students at universities and TVET colleges](#). He said that his department had been engaging with National Treasury on the procurement of learning devices, particularly laptops, for students funded by the National Student Financial Aid Scheme (NSFAS). Minister Nzimande urged higher education institutions to follow the national guidelines when deciding on the return of students, especially at student residences. Measures include that all students and staff, approximately two million people, are required to register for the HealthCheck app – an initiative launched by HIGHER HEALTH as a daily screening and monitoring tool for the higher education sector – and use it every day to assess their own level of risk prior to entering campuses. HealthCheck is available on various platforms – see information here:

1. Dial using USSD line (does not require data): \*134\*832\*2#
2. Add to WhatsApp contacts: 0600 11 0 000 and say HI: <https://wa.me/27600110000?text=hi>
3. Download using the URL for the webform: [healthcheck.higherhealth.ac.za](https://healthcheck.higherhealth.ac.za)

- Analyst Alex Van den Heever from the Wits School of Governance argues in the [Daily Maverick](#) that government only appears to be transparent about COVID-19 strategies including the lockdown and progress of trace/test and scaling up bed capacity for critically ill. In his opinion, "... matters of substance are carefully avoided or fobbed off."

## CLINICAL, SCIENTIFIC

- [People with TB and HIV have a two to three-fold increased risk of dying of COVID-19](#), according to data released by the Western Cape health department. Although the data shows an

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one in 10 fatalities from the new coronavirus was due to being HIV positive and 2% were due to having active TB, departmental public health medicine specialist Mary-Ann Davies announced during a webinar. "[Until now] we haven't known whether we should consider people with HIV as being at higher risk [for COVID-19] or not," said Davies. "So we should consider them as a risk group, both people with HIV and TB, but that increased risk is relatively small." But she added that many deaths among people living with HIV occurred in those with [other underlying health conditions](#), such as diabetes, obesity, high blood pressure and asthma/chronic respiratory conditions.

- According to the latest research published in the Annals of Internal Medicine, the [odds of a false negative through RT-PCR, the most commonly used test \[nasal swab\], is one in five](#). Further research from the Geisel Medical School of Dartmouth suggests that even more emphasis should be placed on addressing these inaccuracies, as testing is crucial to containing the pandemic. According to lead author, Prof Steve Woloshin from the Geisel School of Medicine at Dartmouth and of the Dartmouth Institute for Health Policy and Clinical practice, there are two ways in which the current diagnostic tests, which involve a swab from the nasal passage, can be inaccurate: "A false-positive result mistakenly labels a person infected, with consequences including unnecessary quarantine and contact tracing. [Secondly], false-negative results are far more consequential because infected persons who might be asymptomatic may not be isolated and can infect others," he stated in a news release.

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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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