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COVID-19 news from SAMED, Government and Abroad.



### 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)

**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](#)



BUSINESS FOR SA | COVID-19

### B4SA UPDATE: BUSINESS FOR SOUTH AFRICA WELCOMES RISK-ADJUSTED REOPENING OF THE ECONOMY

- Supports stringent health and hygiene protocols for all public and private sector activity
- Calls for evidence-based interventions balancing health, economic recovery and societal impact
- Commends the commitment of health workers and volunteers in the fight against COVID-19

Business for South Africa (B4SA) supports President Ramaphosa and the Cabinet's decision to continue the phased and risk-adjusted transition of South Africa to Level 3 which enables more businesses and

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As business we believe the ability for any country to deliver better comprehensive health outcomes for all citizens is dependent on a functional society and economy. This means balancing health and economic activity. Wherever possible, every part of South African society – whether the State, business, NGO or individuals, must work in the safest possible manner. Tragically, COVID-19 will afflict the world and our country for many years to come. Infections and mortalities will rise, but so too will the number of our people who have beaten the virus as our capacity to respond increases.

Business commends the work and sacrifice of healthcare workers who are toiling tirelessly to increase public and private healthcare treatment capacity.

To sustain the impetus for a functional economy we must take practical risk-adjusted steps, due to our current circumstances, ultimately to secure the health of South Africa's people. The restart of the economy needs to be from a different premise, one where everyone is willing to adapt to fight COVID-19. The consistent use of non-pharmaceutical interventions (masks, hand washing and sanitising social distancing) must become second nature for every individual and every organisation. We must all ensure that working practices are adapted to meet the health, safety, and hygiene protocols required to combat COVID-19.

### **The safe reopening of our economy requires behaviour change**

The safe reopening of our economy requires behaviour change from all of us. Because we can expect to live with the virus for an extended period of time, we will have to change the way we conduct our lives. We need to embed the health and safety protocols, and these must become part of our everyday lives.

Tools and guidelines to expedite a safe, effective and structured return to work plan have been communicated (<https://www.return2work.co.za>), while additional safe transport recommendations and protocols to minimise the prospect of transmission and enable the accelerated opening of the economy have been proposed to the government.

We need to quickly restore more people's capacity to earn and enable businesses to function. Failing that, government revenue will fall further and larger-scale job losses and more business failures will become inevitable. B4SA is therefore of the firm view that the current rate of economic decline can be slowed further by a rapid progression through Level 3 while embedding health protocols throughout society in the public and private sectors. There remains an absolute necessity for a further swift easing of economic restrictions. This can only be done against risk-adjusted and evidence-based policy, accompanied by strict health and hygiene measures across all aspects of daily life and by limiting the movement of people where practical.

Additionally, as the country's education system enters its phased re-start process, it will place an added burden on society and business. There is an imperative to ensure that core educational content is delivered in order not to waste an academic year and, wherever possible, business must accommodate the needs of parents so that we can support learners and families with their emotional, health and safe wellbeing.

The strong and collaborative partnerships and dialogue underway between government, business, labour and civil society are resonating, and this will significantly strengthen our ability to protect the health of South Africa's people and the economy. [\*\*In the spirit of social solidarity, we also call for good governance, transparency and ethical practice from all social partners in their response to COVID-19.\*\*](#)

While the challenges South Africa face in addressing the COVID-19 crisis will pass, rejuvenating our economy and rebuilding society will require our collective focus in the future to accelerate inclusive economic growth and employment.

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## **COVID-19 RETURN TO WORK TOOLKIT**

As the country moves to Level 4 stage of Lockdown, the President has identified a few key considerations that affected business will need to build into their Return to Work considerations. This is not an attempt to identify each and every requirement as the needs, regulations and requirements of every business will differ. It is a general guideline seeking to identify key considerations for organisations as they navigate the coming months. Demanding a strategic, yet hands-on, flexible thinking.

Download the Return to Work Toolkit [here](#).

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## **CONFIDENTIALITY & COVID-19: EKA SNAP SESSION**



The Disaster Management Regulations and the Notifiable Medical Conditions Regulations authorise the **collection, use and disclosure of personal information**, including health information and information on age and addresses.

Employers are expected to keep a list of employees 60 years and older, as well as all employees with co-morbidities. Screening criteria are applied by health facilities and businesses to visitors, (prospective) patients, company representatives, etc. Tests are expected and results are to be disclosed in some cases. Vast amounts of personal information is collected, stored, used, and in, some cases, passed on to others. This raises important compliance questions.

As limitations to the right to privacy are constitutionally determined, **pertinent questions** will be addressed:

- *Are these disclosures mandatory? Can someone refuse to provide this information?*
- *What can, or must, an employer or a business do with this information? To whom can it be disclosed, if at all?*
- *How can or should this information be used?*
- *Can the Department of Labour, the NDoH / NICD or third parties insist on accessing this information?*
- *How should businesses, practices and employers protect this information? Should it be destroyed and if so, at what stage?*
- *If an employee or visitor is being quarantined, should that fact be disclosed to protect others, or not?*

For more information, contact: [pat@elsabeklinckassociates.co.za](mailto:pat@elsabeklinckassociates.co.za)

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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.



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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](#).



## IMPORTANT SAHPRA MEDICAL DEVICE 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](#)

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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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## 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 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

### WEBINAR INVITATION: EXECUTIVE REMUNERATION

Bowman's invites you to join members of their Employment and Benefits and Tax Practices for a **FREE** virtual discussion on executive remuneration.

The discussion will focus on:

- The latest remuneration responses to COVID-19, including approaches to base pay (increases/cuts/donations), benefits and short- and long-term incentives.
- Share plans and remuneration trends, including ESOPs, executive share plans and incentives, performance conditions and minimum shareholding requirements.
- Shareholder activism broadly, and in particular, Malus and Clawback and other methods of consequence management.
- The legal issues regarding malus and clawback.
- Legal risks associated with the application of discretion.
- The pay gap, living wage and optimising the financial wellness of workers using innovative benefits, including existing tax benefits for workers (housing, education).

**Date:** 26 May 2020, 10:00 - 11:00

**Please click [here](#) to register**

For further information, please contact Simon Dodd at [simon.dodd@bowmanslaw.com](mailto:simon.dodd@bowmanslaw.com) or on +27 72 376 5777.

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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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