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SAMED COVID-19 NEWS

south african medical technology industry association

COVID-19 news from SAMED, Government and Abroad.

INDEX:

1. [SAMED on COVID-19](#)
 - 1.1. [SAMED compliance guidance on emergency support during COVID-19](#)
 - 1.2. [SAMED library](#)
 - 1.3. [SAMED Press Release - Know your coronavirus mask](#)
 - 1.4. [SALDA/SALDA Regulatory Forum](#)
 - 1.5. [COVID-19 products and company information portal](#)
 - 1.6. [SAMED FAQ](#)
 - 1.6.1. [FAQs on Essential Goods, clearance and movement of goods and service](#)
 - 1.6.2. [FAQs on Employees' Tax, ETI and Provisional Tax](#)
2. [COVID-19 Updates, Notices, Legislation & Regulations](#)
 - 2.1. [From the President's Desk](#)
 - 2.2. [Updated SARS ITAC VAT rebate list of critical medical supplies](#)
 - 2.3. [SARS rebate items 412.11 & 621.08 extended](#)
 - 2.4. [SAHPRA medical device hotline](#)
 - 2.5. [Make sure you have read these SAHPRA Medical Device notices](#)
 - 2.6. [National Treasury on COVID-19 implications on the economy and budget](#)
 - 2.6. [Opportunities: American Enterprise on COVID-19 response](#)
 - 2.6. [The solidarity fund](#)
3. [COVID-19 Events](#)
 - 3.1. [BSA Update: Risk assessment presentation](#)
 - 3.2. [AHF-WHO COVID-19 dialogue on private-public collaboration](#)
4. [COVID-19 Developments](#)

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](#).

[Back to top](#)

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](#).

SAMED Press Release - Know your coronavirus mask:

Highest safety, quality and efficacy standards essential for COVID-19 response

The public and everyone involved in eliminating the SARS-CoV-2 virus needs to be vigilant of the standards and guidelines that apply to products used to prevent, diagnose and treat COVID-19. Since the new coronavirus reached South Africa, the procurement and manufacture of crucial items including sanitisers, masks, gloves and other personal protective equipment (PPE), and tests have been

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and wants to support and guide other medical device suppliers to ensure that the provision of these products is done by companies that, if relevant, have been licensed by the SA Health Products Regulatory Agency (SAHPRA), and comply with the necessary safety, quality and efficacy standards.

SAMED collaborates with authorities, SAHPRA, the SA Bureau of Standards (SABS), the National Regulator for Compulsory Standards (NRCS) and other credible entities to assist local manufacturers and importers in following the regulations and is engaging with a range of stakeholders to find ways to ramp up local production of PPE and other related items.

“The critical need for products related to the COVID-19 response has attracted companies which have little or no presence in the South African market. It can be difficult to distinguish *bona fide* suppliers from more opportunistic and unscrupulous suppliers. We appreciate the collaboration with industry including SAMED so we can safeguard patients and medical personnel, and achieve optimal healthcare outcomes,” says Dr Boitumelo Semete-Makokotlela, the CEO of SAHPRA.

“The COVID-19 epidemic has emphasised the role of medical technology in providing safe and effective care and enabling and protecting healthcare professionals and the public. SAMED is committed to working with members, and all medical device suppliers and stakeholders to strengthen South Africa’s efforts to meet the demand for care and save lives,” said Ms Govender Bester.

Download the Full Press Release [Here](#).

[Back to top](#)

SAMED-SALDA Regulatory Forum: SAHPRA Licencing and amendments - A beginners guide

SAMED / SALDA Regulatory Forum

12 MAY 2020



Programme: *subject to change*

09h45	Log-on via Microsoft Teams link (please mute and turn off video when joining)
10h00	Welcome <i>Madeleine Pearce, SAMED Regulatory Committee Chairperson</i>
10h05	Understanding the SAHPRA licencing Process <i>Andrea Julsing-Keyter, Deputy Director Medical Devices, SAHPRA</i> <ul style="list-style-type: none"> • SAHPRA licencing process – a step by step guide <ul style="list-style-type: none"> • Forms to complete; Required documents; Cover letter; Important considerations; Who to contact/where to submit; Time frames • SAHPRA licencing amendments <ul style="list-style-type: none"> • When to submit a notice and when to apply for an amendment; Required documents; Important considerations; Who to contact/where to submit; Time frames • SAHPRA licencing/amendment in light of COVID-19 – an expedited process <ul style="list-style-type: none"> • Who should make use of this process; Who to contact/where to submit; Time frames • COVID-19 Matters <ul style="list-style-type: none"> • NRCS mask & disinfectant requirements & processes; • Serological test kits requirements and processes • SAHPRA appeals process
11h05	Q & A Session with the Regulator <i>Sarah Cohen, Executive Officer, SALDA will facilitate questions with the regulator.</i> Please make use of the comment/chat stream to post questions
12h00	End

Click the link to Join

This will be a virtual meeting held via Microsoft Teams

Please only click the link at the above, specified date/time.

[Join Microsoft Teams Meeting](#)

[Back to top](#)

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 overwhelming demand currently being experienced in South Africa during the weeks to come. 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

From the President's Desk

Since the beginning of May, when we began the gradual easing of the nation-wide coronavirus lockdown, many people have started returning to work. As part of the phased recovery of the economy, companies in certain specified industries have been able to resume part or all of their operations.

The national coronavirus alert level is now at 4, which means that extreme precautions remain in place to limit community transmission. Our goal is to steadily reduce the alert level by keeping the rate of infection down and getting our health system ready for the inevitable increase in cases. As the lockdown is gradually eased, life will slowly return. But it will not be life as we knew it before. Our success in overcoming the coronavirus will ultimately be determined by the changes we make in our behaviour.

Like we have done, many countries are implementing extensive stimulus packages to strengthen their respective health care sectors, support ailing industries and workers and provide relief to

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As the restrictions on economic activity and daily life are eased, it is vital that all South Africans maintain that firm sense of personal responsibility. In all that we do, in every sphere of life, we must take care of our own health and the health of others. Whether as individuals, employers, employees, government, civil society, trade unions or businesses, we will all continue to have a role to play in fighting the pandemic.

The transition to the next phase of the coronavirus response, that of recovery, will be more difficult than the present one. The risk of infection outbreaks will increase. The demands on our clinics and hospitals and medical personnel will grow. That is why easing the lockdown restrictions must not result in careless behaviour by individuals or reckless practices by businesses keen to resume activity at the cost of human health.

The coronavirus crisis will pass. But for as long as it remains a threat to the lives of our people, we must remain vigilant, diligent and responsible. Now, more than ever, it is upon the conduct of each that depends the fate of all.

Cyril Ramaphosa

Download the full letter [here](#).

[Back to top](#)

SARS ITAC VAT Rebate updated published 8 May

SARS has updated the list of critical medical supplies required for COVID-19 which are eligible for the ITAC VAT rebate 412.11. The revised list includes a revised classification of plastic face shields from 3926.20 to 3926.90.

Download the list [here](#).

[Back to top](#)

SARS rebate items 412.11 & 621.08 related to the import or manufacture of essential goods and critical supplies

SARS communiqués issued on 3 April 2020 and 9 April 2020 related to rebate item 412.11 (rebate of duty) and VAT exemption remain in place until 31 May 2020 as the period of validity, until further notice.

Download the notice [here](#).

[Back to top](#)

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](#).

[Back to top](#)

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

[Back to top](#)

Briefing by National Treasury on the financial implications of COVID-19 on both the economy and the budget

The JT Standing Committee and the Select Committee on Finance and Appropriations presented their findings on 30 April with regards to the impact COVID-19 would likely have in the medium term on both the economy and SA national budget. From the presentation, it is clear that much-needed reforms remain relevant for both agriculture and trade. The presentation also covers the emergency procurement provisions with instructions on the emergency procurement of PPE items and cloth masks.

Download the presentation [here](#).

[Back to top](#)

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- **Technical Assistance** for accessing new markets or boost production capacity
- **Financing** as USAID can directly purchase assets that will unlock or expand local manufacturing of medical equipment and supplies
- **De-risking** investments by aggregating demand or supply for commodities.

If you are interested in mobilizing your local manufacturing capabilities or partnering with other companies, please provide the following information to Phil Roberts, Lead, Project Last Mile (phil@projectlastmile.com):

1. What can you donate/produce/offer?
2. In what quantities?
3. Do you require co financing to begin or expand production?
4. Do you require technical assistance? If so, what kind of assistance?
5. Do you have technical assistance to offer?

Download the call [here](#).

[Back to top](#)

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

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

[Back to top](#)

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

[Back to top](#)

AHF-WHO COVID-19 Dialogue

**A PUBLIC-PRIVATE DIALOGUE:
HOW CAN WE WORK TOGETHER
TO COMBAT
COVID-19 IN AFRICA**

Organization

**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

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 Africa Healthcare Federation

[Back to top](#)

COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC



Gauteng	Western Cape	KwaZulu Natal	Free State	Eastern Cape	Limpopo	Mpumalanga	North West	Northern Cape
1,952	5,168	1,353	135	1,218	54	61	45	29
Daily Increase								
42	359	45	1	140	3	0	4	1



LOCKDOWN DEBATE HOTS UP

- COVID-19 media coverage has increasingly focused on the pros and cons of the lockdown.
- [Saul Musker from the Presidency](#) argues that the lockdown has worked, it was the right thing to do, and it won't last forever.
- [Profs Quarraisha and Salim Abdool Karim advise that life must return to normal](#) to help the country deal with the COVID-19 peak infection rate, which is expected to hit by August or early September. Both professors serve on the ministerial committee that advises President Cyril Ramaphosa on SA's Covid-19 response. They say the lockdown has a limited ability to prevent COVID-19 from spreading, as it can only slow it for a short while.
- According to [infectious disease expert Professor Shabir Madhi](#), continuing the lockdown will not stop the wave of community transmissions from hitting South Africa, and continuing it will prolong the collateral damage that it is causing.
- Professor Michael Levitt, the Pretoria-born academic, won the Nobel Prize for Chemistry in 2013. Prof Levitt, who heads Stanford's Medicine's Structural Biology department, [believes](#) that lockdown policies are "a huge mistake" and says if the world had paid closer attention to the way China dealt with the threat of COVID-19, governments elsewhere would have reacted very differently. Instead of closing down the economy, the approach would be: "If we were to do this all again, we'd insist on face masks, hand disinfecting substances and some form of payment system that does not involve touching (ie phones, not credit cards or cash) - and only isolating the elderly."

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social development provide their views on what SA will look like after COVID-19.

- Harambee Youth Employment Accelerator and the National Youth Development Agency are running a campaign to reach three million youth. Their research in the first three weeks of South Africa's lockdown showed [how young people perceive the crisis](#) and how important it is to make sure they have accurate information to keep themselves safe and informed. Key issues that concern the youth are:

1. Scourge of fake news
2. Hope for medical care (they want to know who is recovering, not just who is dying)
3. Staying employable
4. Alternative ways of earning
5. Ongoing skill-building.

CLINICAL & SCIENCE NEWS

- South Africa is only expected to reach the peak of the COVID-19 coronavirus in August or September, but the [Actuarial Society of SA \(Assa\)](#) has warned that as many as 48 000 people could die if the country fails to flatten the curve. Public health specialists have suggested that now may be the time to move from surveillance of the disease and active case-finding to **focusing on hotspot areas**, which would mean intervening in the clusters where the disease has been shown to be problematic. They argue that this change in strategy is necessary as the community screening intervention process – which saw 28 000 community healthcare workers go door-to-door in vulnerable communities to screen and test symptomatic people – has not quite yielded the detection of cases that was anticipated.
- Health care company Johnson & Johnson says they are looking to [produce a billion coronavirus vaccines next year](#), according to the company's Chief Scientific Officer. Dr Paul Stoffels told ABC News the company is upscaling manufacturing and will start producing the vaccine later this year.
- Thomas Polen, the CEO of BD (Becton Dickinson), the world's largest manufacturer of syringes, said that “unless we act now there won't be enough capacity” to quickly [ramp up production to 1 billion syringes for an expected COVID-19 vaccine](#) because of “extreme surge demand,” adding a potential new wrinkle to the overtaxed medical supply chain. BD is in discussions with the US government on the COVID-19 response. Polen is concerned that governments globally should think ahead.

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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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