

## **SAMED COVID-19 Frequently Asked Questions**

Disclaimer: The South African Medical Technology Industry Association (SAMED) is providing this opinion as guidance in the context of current legislation, relevant codes and policies, as well as industry practice, where available. The advice is provided on the basis of the information submitted by the requester. The advice is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions, or, liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the advice provided.

### **Lockdown Protocols – Company Operations**

<b>Which companies are considered essential goods and services companies? How do I know if my company will be allowed to continue operating under the lockdown?</b>
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The categorisation of essential goods and services have been published as an Annexure D of the updated Risk-adjusted Strategy Regulations, (“Regulations”) which you can access <a href="#">here</a> .
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<b>Who do we need a certificate from government to be allowed to trade during the lockdown?</b>
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Yes. It is essential to register your business on the CIPC website - <a href="http://www.bizportal.gov.za">www.bizportal.gov.za</a> . Please follow the instructions on the site. Please keep trying as the website may well be overloaded. It must be noted that companies may trade although certificates have not yet been issued, PROVIDED that they fall within the scope of provision of essential/permitted goods and services as provided under the Regulations and have applied for the certificate, and if there is a delay in obtaining the certificate, companies must seek professional assistance.
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When prompted for you enterprise number enter your company registration number. This will then automatically populate the fields and you can follow the instructions to getting your certificate.
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<b>Will logistics service providers be able to operate during the lockdown? What will they require from me?</b>
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Yes, they will be able to operate during the lockdown as they are providing an essential service to the healthcare industry. You will, however, need to provide their head office with a letter stating that they are your logistics partner and are required by you in order to deliver/ship goods on your behalf. It may be beneficial to also include a copy of the CIPC certificate as evidence that you are permitted to trade during this time. These companies must also supply their employees with permits and obtain the CIPC Certificate for Essential Services.
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<b>Will suppliers to medical manufacturers be allowed to continue operating under lockdown? i.e. suppliers of components or raw materials</b>
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The categorisation of essential goods and services during lockdown have been published as an Annexure D of the updated Risk-adjusted Strategy Regulations, (“Regulations”) which you can access <a href="#">here</a> . We advise that manufacturers of medical technologies provide their supplier with a letter indicating that they are an essential part of the supply chain. However, these companies must also supply their employees with permits and obtain the CIPC Certificate for Essential Services.
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### **How do I obtain a “permits” for all staff, including myself, who will be travelling during the lockdown?**

Use Form 2 on page 29 of the updated Risk-adjusted Strategy Regulations, which you can download [here](#). We advise to add this onto a company letter. Complete the form and ensure that the head of the company (CEO/MD/GM) signs the annexure – your staff will need an originally signed permit and not a copy. The staff will always need to carry this permit together with identification (passport/identity document) and a copy of the CIPC certificate on them.

Additional to this it may be beneficial to also carry a letter from your company with the following details:

- The letter must be an original company letterhead (in colour if possible).
- The full name/'s, Surname, ID number and address of the employee and short Job Description.
- The letter must describe the services provided by the company in order to indicate that they provide essential services.
- The employer's name and address and official business stamp.
- Mention that the staff member might need to be allowed to travel after business hours/irregular hours.
- Name and contact number of CEO.
- Original signature of CEO.

It is essential that your staff be provided with a hard copy of all the above documentation should they be stopped while performing company operations.

### **Do I need to produce multiple permits should I have regional offices?**

The certificate can be used nationally - and does not restrict business to one province or district. Kindly ensure that all essential employees have the requisite permits to work, travel to work and for work and list all premise/addresses applicable.

### **Will staff who are travelling be required to wear protective gear?**

Persons in a public space may be refused entry into a building or public transport if they are not wearing a mask. Please note that they cannot be arrested for not wearing a mask and all such instance must be reported to the authorities.

### **What must I do from an occupational health and safety point of view when considering staff returning 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 (those regulations are still being awaited).

For health facilities and HCPs: As physical distancing can, for example, not be practised when attending to a patient, a separate set of rules are expected. However, it is anticipated that many of the rules in the attached will, in any event, be applicable.

Download the directive [here](#)

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

### Will my company still be required to meet Transformation targets?

The Commission for Employment Equity (CEE) recognises the catastrophic impact of the COVID-19 on the various sectors of the economy and acknowledges the fact that it will be business will be exploring various COVID-19 Response and Recovery Plans with regard to Business Continuity.

In response to the inevitable consequences of the COVID-19 on organisations and in particular, on the implementation of employment equity in the various workplaces, the CEE request all designated employers to take into account the following guidelines:

1. All employers are reminded that they are still legally obligated to comply with all the provisions of all employment laws during their organisational restructuring/ configuration processes to ensure that there is no unfair treatment and unfair discrimination policies and practices against all employees.
2. All designated employers are requested to strive not to reverse the previously attained transformation gains, including to where reasonably practical, achieve their initially planned annual EE targets for 2020. In instances that it is practically not possible to maintain and achieve the initially planned EE targets, the employers may consider reviewing and amending their EE Plans in consultation with the EE Consultative Forums (Sections 16)
3. All designated employers are still required to submit their annual EE Reports as prescribed by Section 21 of the EEA and the EE Regulations, 2014 from 1 September 2020 until 15 January 2021. This EE data is critical in assessing the impact of the COVID-19 on the transformation agenda of the labour market and society as a whole. There is no legal provision for exemptions, condonations or appeals in the EEA for submission of EE Reports.
4. However, in instances where the designated employer is unable to submit an EE Report as per Section 21 of the EEA, such an employer must notify the Director-General of Department of Employment and Labour in writing with reasons before the last working day of August of 2020 as prescribed by Section 21(4A) of the EE Amendment Act, 2013 and the EEA14 form in the EE Regulations, 2014. The reasons that can be advanced as per the EEA14 form, include Section 197 of the LRA; Mergers/ Acquisitions; Labour Court Order; Liquidations/ Judicial Winding; Insolvency; and Other reasons (e.g. employer no longer designated because of size and/ turnover, or company closed down because of retrenchments, or company under business rescue, etc.).

All completed EEA14 forms must be accompanied by supporting documents as proof and must be emailed to [ntsoaki.mamashela@labour.gov.za](mailto:ntsoaki.mamashela@labour.gov.za); [lucia.rayner@labour.gov.za](mailto:lucia.rayner@labour.gov.za); [tshililo.siobo@labour.gov.za](mailto:tshililo.siobo@labour.gov.za); before the last working day of August 2020. Guidelines on how to process DG Notifications and the EEA14 form are available on [www.labour.gov.za](http://www.labour.gov.za)

### Can I have duties on COVID-19 products waived in order to reduce rising import costs?

Duties have been waived in favour of reducing the cost associated with importing medical technology critical to the prevention, testing and management of COVID-19 in South Africa. The Department of Trade, Industry and Competition has made a provision of rebate item 412.11 for goods imported for the relief of distress. Should your import item be listed as [a remedy for critical medical supplies for COVID-19](#), you can download a [rebate application form](#) from the [ITAC website](#) for a duties rebate.

This Standard Operating Procedure (SOP) acts as a guideline for Business in importing critical supplies into South Africa under Rebate Item 412.11. Importantly, rebate item 412.11' means the full rebate of custom duties and VAT exemption on the critical supplies during the COVID-19 pandemic.

**Download the SOP for Business Importing Critical Supplies [here](#).**

Kindly note that a permit application for critical medical supplies as listed on ITAC's website must be submitted electronically to the following officials:

For goods classifiable under Chapter 1 to 68:

- Mr Christopher Sako at [csako@itac.org.za](mailto:csako@itac.org.za); and
- Ms Khosi Mzinjana at [kmzinjana@itac.org.za](mailto:kmzinjana@itac.org.za);

For goods classifiable under Chapter 69 to 96:

- Ms Lufuno Maliaga at [lmaliaga@itac.org.za](mailto:lmaliaga@itac.org.za)

It should also be noted that the relevant application form requires among others, specific volumes and values, which should be informed by i.e. offtake orders or substantiated methodology that supports the volume applied for as well corresponding value. It would therefore not be a blanket permit for a prolonged period of time.

Should you require more clarity you are at liberty to contact the relevant officials mentioned above.

### Where can I get a list of goods that are banned from export by government?

The restriction on Personal Protective Equipment are set out in the published [Export Regulations](#).

The regulation provides that items listed in schedules 1,2,3 and 4 shall not be exported from the Republic of South Africa except by virtue of an export permit issued in terms of Section 6 of the said International Trade Administration Act,2002.

Schedule 4 was added and the lists items such as masks (PPE) and sanitisers which in addition to the existing list which can now not be exported without permits.

### With who do I register and what documents do I need to export products during the lockdown?

ITAC import or export permit applications for disaster relief as a result of COVID-19 must be submitted electronically to Marius Collins Import & Export Control via [mcollins@itac.org.za](mailto:mcollins@itac.org.za).

You will need to complete the following documents:

[IE361 Application or export permit: General Goods](#)

[IE230 Application to register as an exporter or change of current information](#)

**Who do I contact at ITAC to assist me with my exports application?**

ITAC import or export permit applications for disaster relief as a result of COVID-19 must be submitted electronically. Exemptions for exports all need to be directed to Marius Collins and Lufuno with the correspondence copied to Mohamed Vawda on all ITAC related issues.

- Marius Collins [mcollins@itac.org.za](mailto:mcollins@itac.org.za)
- Lufuno Maliaga [lmaliaga@itag.org.za](mailto:lmaliaga@itag.org.za)
- Mohamed Vawda [MVawda@economic.gov.za](mailto:MVawda@economic.gov.za).

You will need to complete the following documents:

- [IE361 Application or export permit: General Goods](#)
- [IE230 Application to register as an exporter or change of current information](#)

More details can be found on the [ITAC Communication to Stakeholders](#).

**Will stock deliveries at ports of entry be allowed and will clearing agents still be able to make deliveries from ports of entry to suppliers during lock down?**

Clearing Agents permitted that is, providing essential services in terms of [Regulations](#) must be allowed to clear essential goods. SAHPRA and NRCS have indicated that certain essentials such as masks and serological tests will be required to prove they are effective/conform to the standards before they will be cleared at the ports of entry. Please ensure that you do this well in advance of arrival of stock.

**Could anyone please guide me on the implications (import and export) when removing “spare parts (non-medical device)” from our site licence product list? Or would you recommend we list these spare parts with the products it is used for?**

There is no need to list spare parts on your license.

**COVID-19 Solidarity Fund****My company/I want to contribute/donate funds/products towards the SA COVID-19 efforts. How should I go about this?**

The Solidarity Fund, established by President Ramaphosa will be a rapid response vehicle through which individuals and organisations will be able to support South Africa’s mobilisation against COVID-19 through secure, tax-deductible **monetary donations**. The Chairperson of the Fund is Ms Gloria Serobe and the Vice-Chairperson is Mr Adrian Enthoven and will operate with the highest principles of corporate governance. All activities will be reported in a transparent manner.

**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)

## Regulatory Matters

### The SAHPRA Medical Device Establishment deadline is 31 March 2020. In the case where submissions to SAPHRA remain unanswered, what procedures should be followed?

SAHPRA recently [extended the deadline](#) to use the acknowledgement letter in lieu of your Medical Device Establishment Licence to 17 April 2020.

**SAHPRA has updated how stakeholders engage with them during the Pandemic.** SAHPRA will continue working and its operations will continue. Please note that all permits, certificates, licences, recommendations, resolutions and letters will not be collected from SAHPRA offices during this lockdown period. These will be e-mailed to applicants.

SAHPRA also 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

### What are the requirements to supply medical masks?

The NRCS has put forward the following:

#### **For Sales Permit:**

- Sales Permit application form (including the compulsory table)
- Motivation letter
- Test reports **(in English)**, if available, to the standards mentioned
- Information for the user
- Clear Photographic evidence of mask and packaging

#### **For full homologation:**

- Homologation application form
- Test reports, if applicable, to the standards mentioned
- Information for the user
- All photographic evidence of mask and packaging.

In the wake of the Covid-19 and the resultant shortage, NRCS is using the sale permit route for temporary approval. They still require test reports to prove compliance. The following minimum tests are required:

- Total inward leakage
- Particle penetration;
- Breathing resistance;
- Flammability;
- Practical performance (check face fit and comfortability)

For N95/KN95 masks, NRCS will test according to above, SANS 50149 and EN 14683. And will need to be licenced by SAHPRA for medical/health sector use. NRCS selected the most critical tests for the different products. This is only a temporary agreement with manufacturers and distributors,

therefore after this critical period, you must ensure the full testing of your products for approval (homologation).

**For local testing only:**

Protechnik Laboratories a Division of Armscor SOC Ltd

103 Combretum Crescent, Highveld Techno Park, Centurion, Gauteng PO Box 8854, Pretoria, 0001

Tel: +27 12 665 9431 | Fax: +27 12 665 0240 |

E-mail: martinm@protechnik.co.za web [www.armscordi.com](http://www.armscordi.com)

All application to be emailed to [CMMAPPROVALS@nrccs.org.za](mailto:CMMAPPROVALS@nrccs.org.za)

**NB:** Kindly note that the type of mask, the intention of the masks, the environment in which mask is used and the sterility of the mask determines the regulatory pathway of said mask.

Medical and surgical masks are classified as Class A medical devices. Further masks claiming sterility are classified as Class A medical devices with sterility and require the establishment (manufacturer, distributor) to be licensed with SAHPRA under Act 101. In addition, compliance to SANS1866 is mandatory. If the mask is not making claims to protection of viruses or being used by medical personnel and is specifically for civilian use, which should be specifically labelled as such, then these fall outside the mandate of SAHPRA and the NRCS regulations.

If a medical mask is indicated on the label, the SANS1866 standard must be complied with can be tested by Protechnik for compliance.

- For Medical (Surgical) Mask/Respirators SANS 1866:2018 or EN14683 or equivalent.
- For Surgical Mask tested to EN14683 or equivalent. Must be sent to SAHPRA, not NRCS

1. [Joint Communication to Stakeholders Regulatory Status of Equipment Being Used to Help Prevent Coronavirus \(COVID-19\)](#)
2. [CMM FM 8072-1-2012.1 - Items required for the approval of RPDs](#)
3. [CMM FM 8072-2-2012.1 - Technical file for RPDs](#)
4. [CMM FM 8072-3-2012.1 - Application for the approval of a type of RPD](#)
5. [CMM FM 8072-4-2012 - Test Reports](#)
6. [CMM FM 8072-5-2012.1 - COP & routine tests - Filtering devices](#)
7. [CMM FM 8072-6-2012.1 - COP & routine tests - BA](#)
8. [CMM FM 8072-7-2012 - Application for the extension of approval of a type of RPD](#)
9. [Levies & fees 2019](#)
10. [NRCS Levy Registration Form](#)
11. [SALES PERMIT application form](#)
12. [VC8072](#)

For more information visit the [NRCS website](#).

**What are the requirements to supply chemical disinfectants?**

The following documents are required for an application for the new product registration or modification or extension of registration of a chemical disinfectant formulation:

- Proof of payment of the non-refundable application fee for the modification or extension of registration of the chemical disinfectant formulation as published in the Government Gazette in terms of section 14(3)(b) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008). The amount of the non-refundable application fee may be requested from the NRCS CMM Approvals Section
- Completed and signed NRCS form No. CMM FM 8054-4
- Information of manufacturing plants and warehouses (see item No. 2 on NRCS form No. CMM FM 8054-2)
- List of raw materials and active substance(s) and their concentration(s) for the chemical disinfectant formulation (see item No. 3 on NRCS form No. CMM FM 8054-2);
- SDS satisfying requirements of SANS 11014 (see item No. 4 on NRCS form No. CMM FM 8054-2)
- Bill of materials of packaging material (see item No. 5 on NRCS form No. CMM FM 8054-2)
- New product label (see item No. 6 on NRCS form No. CMM FM 8054-2)
- Test reports (see item No. 7 on NRCS form No. CMM FM 8054-2)
- Evidence of QMS certification and product certification (see item No. 8.1 on NRCS form No. CMM FM 8054-2). QMS certificates are only applicable to the chemicals disinfectants used in food and medical areas.
- NRCS form No. CMM FM 8054:6 chemical disinfectants for use in industrial, domestics and institutional areas.

All applications to be emailed to [CMMAPPROVALS@nrscs.org.za](mailto:CMMAPPROVALS@nrscs.org.za)

1. [CMM FM 8054-1-2019 - Items required for the registration of chemical disinfectants](#)
2. [CMM FM 8054-2-2019 - Technical file for chemical disinfectants](#)
3. [CMM FM 8054-3-2019 - Application for the registration of a chemical disinfectant formulation](#)
4. [CMM FM 8054-4-2019 - Application for the modification or extension of registration of a chemical disinfectant formulation](#)
5. [CMM FM 8054-5-2019 - Test reports for chemical disinfectants](#)
6. [Levies & Fees 2019-2020](#)
7. [NRCS Levy Registration Form](#)
8. [SALES PERMIT application form](#)
9. [VC8054](#)

For more information visit the [NRCS website](#).

**What (if any) are the special requirements/procedures needed for e-IFUs?**

There are no special requirements for eIFU's, they are considered labelling as for any other label.

**Supply Chain Management****Where can we find information on the price setting for masks and other medical supplies?**

The DTI has published [regulations relating to pricing of goods and services](#) during the lockdown.



### Where can SMMEs apply for the support offered by government?

SMME are to submit funding application with <http://www.smmesa.gov.za> registration number and supporting documentation to dedicated SEFA email address: [info@sefa.org.za](mailto:info@sefa.org.za). It is important for the businesses to meet [the requirements set out](#) by government.

### I am a business owner. How can I access support during the lockdown?

If you cannot pay the full salaries of your employees:

- Apply for the Unemployment Insurance Fund's COVID-19 TERS benefit by sending an email to [covid19ters@labour.gov.za](mailto:covid19ters@labour.gov.za). You will receive an automated reply with instructions on how to proceed. The fund will contribute a portion of the employee's salary up to a maximum of R17,712 per month for each employee.

If you are in financial distress and require grant or loan funding:

- You must register on <https://smmesa.gov.za/> to be eligible for funding from the Debt Relief Finance Scheme. Once you have registered, you can download the application form on <https://smmesa.gov.za/> or [www.sefa.org.za](http://www.sefa.org.za) and email it to [smmerelief@sefa.org.za](mailto:smmerelief@sefa.org.za).
- Apply for relief funding from the South Africa Future Trust directly through your bank. If you have an account with Standard Bank, FNB, Absa or Nedbank, contact your bank to find out how to access this facility. Visit <https://oppgen.com/saft/> for more information about the scheme. If you have an account with Nedbank, visit <https://www.nedbank.co.za/content/nedbank/desktop/gt/en/business/covid-19-relief1/SAFT1.html>. If you have an account with Standard Bank, visit <https://www.standardbank.co.za/southafrica/business/covid-19/south-africanfuture-trust>.
- Contact the bank where you have an existing account to enquire about payment holidays and options for debt restructuring.

If you produce an essential good or service and require funding to scale up your operations:

- Apply to the Industrial Development Corporation for working capital, loan or trade finance to support your operations. Email [covid@idc.co.za](mailto:covid@idc.co.za), call 0860 693 888, or visit <https://www.idc.co.za/2020/03/24/idc-interventions-inresponse-to-covid-19/> for more information.