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COVID-19 news from SAMED, Government and Abroad.

## THE LOW-DOWN ON LEVEL 2 LOCKDOWN

- **New permits for services delivered during curfew** hours (22:00 - 04:00). A new template has not been issued, and we propose that you change the permit heading to refer to also being issued to "Regulation 50" (and not only regulations 16(2)(b), 28(4) and 33(1a)) or use our template [here](#).
- **Mandates face mask-wearing** (Reg 51), funerals (reg 52), evictions (reg 53) & rental (reg 54). The liquor permission is listed in reg 61.
- Gatherings, including **conferences**, are limited to 50 persons, excluding those participating via electronic forums, and only for business purposes (reg 55(2)(d))
- Further details will be issued by Ministers on issues such as sport, restaurants and bars, **accommodation (which cannot be more than 50% occupied)**, etc.
- Unfortunately, the exact equivalent of the previous regulation 40 is still in place (reg 58), namely that **no visitors other than those receiving healthcare may be present in health establishments**.
- International travel is prohibited, save for limited circumstances (e.g. emergency healthcare (reg 59)).
- Employers with 100 or more employees, and those with 500 or more employees have to comply with the specific provisions in regulation 62, including, amongst others, mandatory submission of data. Provisions on vulnerable employees are still in place. Again, the **Annexure E Plans** and **COVID-19 Compliance Officers** (reg 63) are prominent in the Regulations.
- Table 3 on the prohibited sectors again re-states "**all persons who are able to work from home must do so**". Prohibited sectors are "nightclub" and "international travel for leisure purposes", amongst others. This does seem to permit international business travel, however, this is not made explicit in any of the public announcements.

Download the Alert Level 2 Regulations [here](#).

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## THERE IS NOTHING SMALL ABOUT THE IMPACT SMALL BUSINESSES HAVE ON OUR ECONOMY

This is according to an article posted on the [Small Business Site](#).

South Africa has hundreds of thousands of small businesses and there's **nothing small** about the impact these small businesses have on our country's economy.

Small businesses need the nation to mobilise behind them more than ever before. That's the word from Mike Anderson, Founder & CEO of the National Small Business Chamber (NSBC). The role that small businesses play in job creation, poverty alleviation, service delivery, and wealth creation all mean that small business is big business.

Read more on this and other stories in the [Small Business Site Newsletter](#).

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## GENE VANTAGE REQUIRES AN ISO13485 COMPLIANT FACILITY FOR MANUFACTURE & PACKAGING OF STERILE LIQUIDS

Gene Vantage is looking for an ISO 13485 compliant facility for the manufacturing and packaging of sterile liquids used as IVDs.

The details / requirements are as follows:

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- The product will be filtered and then steam sterilised prior to packaging.
- Packaging from bulk needs to be carried out in a class 7 air zone (10 000 particles per cubic foot). Potentially within a laminar flow or biosafety cabinet.
- Product is currently packaged into round, wide neck HDPE bottles with screw cap lids, volume sizes ranging from 60 ml to 400 ml. Plasticware is EO sterilised prior to use.
- Requires label to be added to plastic bottles, as well as a batch/lot number.
- Confirmation of sterility of product is required on a per batch basis.
- All the required equipment for manufacturing and bottling is available and portable, only the cleanroom space is required.

**If you are able to assist please contact Genevieve Thompson on 079 934 4218 or [genevieve@genevantage.com](mailto:genevieve@genevantage.com)**

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Telephone: 011 704 2440 - Email: [info@samed.org.za](mailto:info@samed.org.za) - [www.samed.org.za](http://www.samed.org.za)

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SAMED is the voice of the South African medical technology industry. The not-for-gain-association 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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