

# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00001556MD\_v2

## LICENCE TO MANUFACTURE MEDICAL DEVICES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965  
To act as a Manufacturer, Distributor, Importer and Exporter

This amended licence replaces the licence issued on the 15<sup>th</sup> of December 2020

This licence is granted to:

Licence Holder  
**Microanalytica Pty Ltd**  
489 Jacqueline Drive  
Garsfontein  
Pretoria  
0081

### On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medical devices distributed, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22H, 23, 26, 28, 33 and the Regulations relating to Medical Devices 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant South African Health Products Regulatory Authority Guidelines.

### This licence consists of 5 pages.

This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

DocuSigned by:

*Boitumelo Semete-Makokotlala*

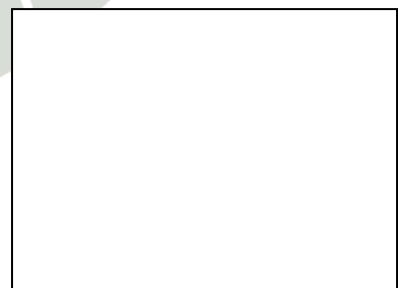
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**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 18 September 2020**

**EXPIRY DATE: 18 September 2025**

**AMENDMENT DATE: 30 July 2021**



*This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.*  
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## ANNEXURE 1

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<b>AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES</b>
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<b>1. MANUFACTURING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
<b>Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as artooning or labelling)</b>		
Single use		No
Measuring medical devices		No
Non-invasive medical device		No
Invasive medical devices		No
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other sterile medical devices (as specified):		No
<b>Non-sterile Manufacture</b>		
Measuring medical devices		No
Non-invasive medical devices		No
Invasive medical devices:		No
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other non-sterile medical devices (as specified):		No
<b>Manufacture of In Vitro Devices (IVDs)</b>		
Class A IVD		No
Class B IVD		No
Class C IVD		No
Class D IVD		No
<b>End point Sterilisation of Medical Devices</b>		No
<b>Manufacture of Radioactive Medical Devices</b>		No
<b>Servicing and Refurbishment of Medical Devices</b>		No
<b>2. PACKAGING ACTIVITIES</b>		
Packaging of bulk product and labelling		No
Re-labelling or redressing	Yes	
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs		No
<b>3. TESTING ACTIVITIES</b>		
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified):		No
<b>4. DISTRIBUTION ACTIVITIES</b>		
Distribution to hospitals and retail pharmacies and other clients: Class A	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class B	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class C	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class D	Yes	

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	YES	NO
<b>5. MATERIALS HANDLED OR STORED AT THIS SITE</b>		
Combination medical devices with Penicillins		No
Combination medical devices with Cephalosporins		No
Combination medical devices with (other) Antibiotics (as specified):		No
Combination medical devices with Hormones		No
Combination medical devices with Cytostatics/Cytotoxics		No
Bulk Pesticides, Herbicides or Rodenticides		No
Radioactive material or Radioactive medical devices		No
Other potent, toxic, sensitising or hazardous materials (as specified):		No
<b>6. IMPORT</b>		
Import Class A medical device	Yes	
Import Class B medical device	Yes	
Import Class C medical device		No
Import Class D medical device		No
Import Class A IVD		No
Import Class B IVD		No
Import Class C IVD	Yes	
Import Class D IVD ( See section 11)	Yes	
Import RUO IVDs		No
<b>7. EXPORT</b>		
Export Class A medical device	Yes	
Export Class B medical device	Yes	
Export Class C medical device		No
Export Class D medical device		No
Export Class A IVD		No
Export Class B IVD		No
Export Class C IVD	Yes	
Export Class D IVD	Yes	
Export RUO IVDs		No

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**8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER**

Authorised Representative	Manufacture / Import / Distribution / Export Control Person	Quality Control Person
Liezel Raubenheimer	Liezel Raubenheimer	Liezel Raubenheimer
Management Advanced Program	Management Advanced Program	Management Advanced Program

**9. PARTICULARS OF THE LICENCE HOLDER CONTACT (Other than the Authorised Representative)**

Name	Contact Details	Address
L Raubenheimer	Tel: N/A Cell: 0829005730 Fax: N/A Email: liezel@microanalytica.co.za	489 Jacqueline Drive Garsfontein Pretoria 0081

**10. LICENCE SPECIFIC CONDITIONS**

- The holder of the licence shall conduct all manufacturing, distribution or wholesaling operations in respect of those medical devices for which a registration certificate has been obtained, so as to ensure that the medical devices shall conform to the standards of quality, safety and performance applicable to them in accordance with the specifications made by the person to whose order they are manufactured, distributed or wholesaled or the specifications under which the medical devices are sold or supplied.

**11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)**

**See amended application (v2)**

- o Section 4.4

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- Regulation 21(1) (a) of the Regulations Relating to Medical Devices and In vitro Diagnostics be followed, A Class C and Class D medical device/IVD may be advertised to Healthcare professionals only
- Xfree™ COVID-19 Direct RT-PCR approved for use only when pre-extracted RNA specimens is used

PRODUCT NAME	PRODUCT DESCRIPTION	ORIGINAL MANUFACTURER	STATUS
BioGX SARS-CoV-2 HMP - N1, N2 & RNase P Multiplex	Molecular	BioGX	Listing Authorised 15/12/2020
Xfree™ COVID-19 Direct RT-PCR (Extraction-Free, Multi-Platform Detection Kit) pre-extracted RNA.	Molecular	BioGX (AL, USA);	Listing Authorised 30/07/2021