

**SOUTH AFRICAN HEALTH PRODUCTS  
REGULATORY AUTHORITY**



**Licence number: 00001933MD\_R1**

**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 and Importer**

**This amended licence replaces the licence issued on the 11<sup>th</sup> of April 2025**

This licence is granted to:

Licence Holder

**Bio-Rad Laboratories (Pty) Ltd**

Spaces Waterfall, Ground Floor Gateway West,  
22 Magwa Crescent, Waterfall City, Midrand,  
Johannesburg, Gauteng  
1685

**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 4 pages.**

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

Boitumelo Semete-Makokotela  
  
SIGNIFLOW

**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 30 April 2021**

**1ST RENEWAL DATE: 24 February 2026**

**EXPIRY DATE: 24 February 2031**

**AMENDMENT DATE: N/A**

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**ANNEXURE 1**

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**AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES**

<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 cartoning 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 Medical Devices (Non – IVDs and IVDs)</b>		
Class A Medical Devices		No
Class B Medical Devices		No
Class C Medical Devices		No
Class D Medical Devices		No
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>	Yes	
<b>2. PACKAGING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging		No
Assembly or “kits” / procedure packs		No
<b>3. TESTING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified):		No

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<b>4. DISTRIBUTION ACTIVITIES</b>	<b>YES</b>	<b>NO</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	
<b>5. MATERIALS HANDLED OR STORED AT THIS SITE</b>	<b>YES</b>	<b>NO</b>
Medical devices stored at licence holder site		No
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>	<b>YES</b>	<b>NO</b>
Import Class A medical device		No
Import Class B medical device		No
Import Class C medical device		No
Import Class D medical device		No
Import Class A IVD	Yes	
Import Class B IVD	Yes	
Import Class C IVD	Yes	
Import Class D IVD	Yes	
Import RUO IVDs	Yes	
<b>7. EXPORT</b>	<b>YES</b>	<b>NO</b>
Export Class A medical device		No
Export Class B medical device		No
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		No
Export Class D IVD		No
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
Sadè Kalichurn-Alphos	Lorine Cassim	Sadè Kalichurn-Alphos
BPharm	None	BPharm

**9. PARTICULARS OF THE LICENCE HOLDER CONTACT (AND AUTHORISED REPRESENTATIVE, if not the same person)**

Name	Contact Details	Address
Ms T Fincham (LH)	Tel: (+27) 11 442 8508 Cell: (+27) 82 522 9823 Fax: (+27) 11 442 8525 Email: <a href="mailto:tracy_fincham@bio-rad.com">tracy_fincham@bio-rad.com</a>	Spaces Waterfall, Ground Floor, Gateway West, 22 Magwa Crescent, Waterfall City, Midrand, Johannesburg, Gauteng 1685
Mrs S Kalichurn-Alphos (AR)	Tel: (+27) 11 442 8508 Cell: (+27) 82 920 9825 Fax: (+27) 11 442 8525 Email: <a href="mailto:regulatory_sa@bio-rad.com">regulatory_sa@bio-rad.com</a>	Spaces Waterfall, Ground Floor, Gateway West, 22 Magwa Crescent, Waterfall City, Midrand, Johannesburg, Gauteng 1685

**10. LICENCE SPECIFIC CONDITIONS**

- 10.1 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.
- 10.2 Once the renewed license is issued to the applicant the current existing license becomes invalid.

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

- 11.1 Only the following unregistered medical device or IVD, listed below, has been granted authorisation for sale in terms of Section 21 of Act 101 of 1965.
- 11.2 Any medical device or IVD sold in pursuance of any authority granted under Section 21(1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

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- 11.3 Distribution is limited to the conditions prescribed in the Section 21 Authorisation and in line with the National Department of Health Testing Strategy and the National Department of Health Clinical Guideline, only.
- 11.4 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 Health Care Professionals only.

<b>PRODUCT NAME</b>	<b>PRODUCT DESCRIPTION</b>	<b>ORIGINAL MANUFACTURER</b>	<b>STATUS</b>
EDX SARS-CoV-2 Negative	Molecular	Exact Diagnostics LLC 3400 Camp Bowie Blvd CBH-214 Fort Worth Texas 76107 United States	Listing Authorised 19/06/2020
EDX SARS-CoV-2 Standard	Molecular	Exact Diagnostics LLC 3400 Camp Bowie Blvd CBH-214 Fort Worth Texas 76107 United States	Listing Authorised 19/06/2020
2019-nCoV CDC ddPCR Triplex Probe Assay	Molecular	Bio-Rad Laboratories, Inc 5731 W. Las Positas Blvd Pleasanton, CA 94588 United States	Listing Authorised 22/09/2020
SARS-CoV-2 Negative Run Control (COV000CE)	Molecular	Exact Diagnostics LLC 3400 Camp Bowie Blvd CBH-214 Fort Worth Texas 76107 United States	Listing Authorised 22/09/2020
SARS-CoV-2 Positive Run Control (COV019CE)	Molecular	Exact Diagnostics LLC 3400 Camp Bowie Blvd CBH-214 Fort Worth Texas 76107 United States	Listing Authorised 22/09/2020
VIROCLEAR SARS-CoV	Molecular	Bio-Rad Laboratories, Inc 5731 W. Las Positas Blvd Pleasanton, CA 94588 United States	Listing Authorised 20/11/2020

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Virotrol SARS-CoV	Molecular	Bio-Rad Laboratories, Inc 5731 W. Las Positas Blvd Pleasanton, CA 94588 United States	Listing Authorised 20/11/2020
Bio-Rad Reliance SARS-CoV-2 RT- PCR Assay Kit	Molecular	Bio-Rad Laboratories. Inc. 4000 Alfred Nobel Drive, Hercules. CA 94547 United States	Listing Authorised 16/07/2021
Platelia SARS- CoV-2 Total Ab assay	Serological	Bio-Rad 3 Boulevard Raymond Poincare. 92430 Marnes-la- Coquette, France	Listing Authorised 11/03/2022 Section 21 Authorisation MD21.202203/06
SARS-CoV-2 Negative Run Control (COV000CE)	Control	100 South Jones Street, Suite 100 Fort Worth, TX 76104, USA	Listing Authorised 18/02/2025
SARS-CoV-2 Positive Run Control (COV019CE)	Control	100 South Jones Street, Suite 100 Fort Worth, TX 76104, USA	Listing Authorised 18/02/2025
RP Positive Run Control	Control	100 South Jones Street, Suite 100 Fort Worth, TX 76104, USA	Listing Authorised 18/02/2025
RP Negative Run Control	Control	100 South Jones Street, Suite 100 Fort Worth, TX 76104, USA	Listing Authorised 18/02/2025

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