SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000540MD_v1

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 24th of April 2018

This licence is granted to:

Licence Holder

Medical Diagnostech (Pty) Ltd
Unit 3 on London
London Circle
Brackengate Business Park
Cape Town
7560

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.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 24 April 2018

EXPIRY DATE: 24 April 2023

AMENDMENT DATE: 22 October 2021

ANNEXURE 1 **00000540MD_v1**

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	**YES**	**NO**
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as artooning or labelling)		
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
Non-sterile Manufacture		
Measuring medical devices		No
Non-invasive medical devices	Yes	
Invasive medical devices:		No
Active medical devices		No
Inactive medical devices	Yes	
Contraceptive medical devices		No
Combination medical devices		No
Other non-sterile medical devices (as specified):		No
Manufacture of *In Vitro* Devices (IVDs)		
Class A IVD	Yes	
Class B IVD	Yes	
Class C IVD	Yes	
Class D IVD	Yes	
End point Sterilisation of Medical Devices		No
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices		No
2. PACKAGING ACTIVITIES		
Packaging of bulk product and labelling	Yes	
Re-labelling or redressing	Yes	
Cartoning or secondary packaging	Yes	
Assembly or “kits” / procedure packs	Yes	
3. TESTING ACTIVITIES		
Analytical	Yes	
Microbiological		No
Sterility		No
Stability	Yes	
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
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
5. MATERIALS HANDLED OR STORED AT THIS SITE		
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
6. IMPORT		
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	Yes	
Import Class B IVD	Yes	
Import Class C IVD		No
Import Class D IVD		No
Import RUO IVDs		No
7. EXPORT		
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	Yes	
Export Class B IVD	Yes	
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
Lyndon Mungur	Ashley Uys	Lyndon Mungur
PhD: Biotechnology	BSc Hons	PhD: Biotechnology

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

Name	Contact Details	Address
A Uys	Tel: '(021) 982 0673 Cell: 0832615492 Fax: N/A Email: ashley.uys@medi-tech.co.za	Unit 3 on London London Circle Brackengate Business Park Cape Town 7560

10. LICENCE SPECIFIC CONDITIONS

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.

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

See amended application

- Section 4.1 and 17.2

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.
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.

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.

PRODUCT NAME	PRODUCT DESCRIPTION	ORIGINAL MANUFACTURER	STATUS
MD COVID-19 IgG/IgM Rapid Test	Antibody Test	Medical Diagnostech (Pty) Ltd	Listing Authorised 22/10/2021 Section 21 Authorisation MD21.2021010/07