

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000095MD_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 18th of September 2019

This licence is granted to:

Licence Holder
IDT Diagnostics t/a ICT International
271 De Goede Hoop Estate
Noordhoek
7979

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.

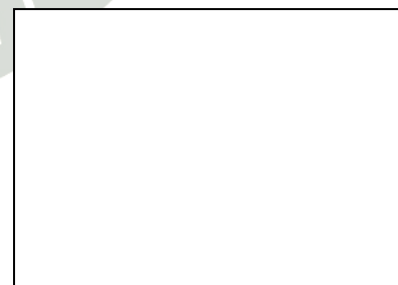
DocuSigned by:

Boitumelo Semete-Makokotlala
CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 02 October 2017

EXPIRY DATE: 02 October 2022

AMENDMENT DATE: 02 March 2021



ANNEXURE 1

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AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES
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1. MANUFACTURING ACTIVITIES	YES	NO
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning 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		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
Manufacture of In Vitro Devices (IVDs)		
Class A IVD		No
Class B IVD	Yes	
Class C IVD	Yes	
Class D IVD		No
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		No
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs	Yes	
3. TESTING ACTIVITIES		
Analytical		No
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		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 (See section 11)	Yes	
Import RUO IVDs		No
7. EXPORT		
Export Class A medical device	Yes	
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
Russell Alton Glanz	Russell Alton Glanz	Robynne Paula Glanz
Chemical Pathology/ Medical Microbiology	Chemical Pathology/ Medical Microbiology	Medical laboratory technology

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

Name	Contact Details	Address
R. P. Glanz	Tel: 021 789 2979 Cell: 082 301 7450 Fax: 021 789 2979 Email: russellag@icon.co.za	Box 912 Noordhoek Cape Town 7985

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 (V2)

- Section 4.4
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.

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PRODUCT NAME	PRODUCT DESCRIPTION	ORIGINAL MANUFACTURER	STATUS
Zhejiang Orient Gene Biotech Coronavirus Rapid Antigen Test	Antigen test	Zhejiang Orient Gene Biotech 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China.	Listing Authorised 02/03/2021
			Section 21 Authorisation MD21.202103/01

