SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 00002410MD

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 licence is granted to:

Licence Holder
BioCertica (Pty) Ltd
Suite B03 Laconcorde Building
57 Main Road
Paarl
Western Cape
7646

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: 05 August 2022

EXPIRY DATE: 05 August 2027

AMENDMENT DATE: N/A

ANNEXURE 1 **00002410MD**

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

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	Yes	
Invasive medical devices		No
Active medical devices	Yes	
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		No
Class C IVD		No
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		No
Assembly of “kits” / procedure packs		No
3. TESTING ACTIVITIES		
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified): software test analysis	Yes	
4. DISTRIBUTION ACTIVITIES		
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B		No
Distribution to hospitals and retail pharmacies and other clients: Class C	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class D		No

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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		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		No
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		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
Jan Vorster	Jan Vorster	Rumon Thirion
Master of Engineering - MEng, Biomedical/Mechatronic Engineering	Master of Engineering - MEng, Biomedical/Mechatronic Engineering	Matric

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

Name	Contact Details	Address
G Van Wyk	Tel: 021 300 6387 Cell: 071 689 2636 Fax: N/A Email: gertvw@biocertica.com	Suite B03 Laconcorde Building 57 Main Road Paarl Western Cape 7646

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)