SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 00003352MD

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 licence is granted to:

Licence Holder

DTD High Technical Healthcare (Pty) Ltd
33 Nightingale Street
Eikenhof Ext 3
Meredale
2091

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-Makokotlela

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 08 December 2023

EXPIRY DATE: 08 December 2028

AMENDMENT DATE: N/A

ANNEXURE 1 **00003352MD**

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	Yes	
Invasive medical devices	Yes	
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		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	**YES**	**NO**
Packaging of bulk product and labelling		No
Re-labelling or redressing	Yes	
Cartoning or secondary packaging		No
Assembly or “kits” / procedure packs		No
3. TESTING ACTIVITIES	**YES**	**NO**
Analytical	Yes	
Microbiological	Yes	
Sterility	Yes	
Stability		No
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES	**YES**	**NO**
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		No

00003352MD

5. MATERIALS HANDLED OR STORED AT THIS SITE		YES	NO
Medical devices stored at licence holder site		Yes	
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		**YES**	**NO**
Import Class A medical device		Yes	
Import Class B medical device		Yes	
Import Class C medical device		Yes	
Import Class D medical device			No
Import Class A IVD			No
Import Class B IVD			No
Import Class C IVD			No
Import Class D IVD			No
Import RUO IVDs			No
7. EXPORT		**YES**	**NO**
Export Class A medical device		Yes	
Export Class B medical device		Yes	
Export Class C medical device		Yes	
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

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
David Tshiamo Ditshwene	David Tshiamo Ditshwene	Hellen Ditshwene
Certificate (Business Management)	Certificate (Business Management)	Diploma (Accounting)

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

Name	Contact Details	Address
Mr. D. T. Ditshwene (LH)	Tel: '(011) 941 8259 Cell: 0723958314 Fax: 0867674565 Email: david.d@dtdhightech.co.za	P O BOX 1069 Houghton Johannesburg 2041
Mrs. K. H. Ditshwene (AR)	Tel: '(011) 941 8259 Cell: 27825506962 Fax: 086 767 45 65 Email: hellyd@dtdhightech.co.za	33 Nightingale Street Eikenhof EXT 3 Meredale 2091

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)