SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000620MD_v1R1

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 01 November 2022

This licence is granted to:

Licence Holder

Marcus Medical (Pty) Limited
63 Old Pretoria Main Road
Halfway House
Midrand
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-Makokotlela
31/10/2023 15:17:58(UTC+02:00)

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 24 April 2018

1ST RENEWAL DATE: 01 November 2022

EXPIRY DATE: 01 November 2027

AMENDMENT DATE: 13 October 2023

ANNEXURE 1 **00000620MD_v1R1**

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		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		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	Yes	
2. PACKAGING ACTIVITIES	**YES**	**NO**
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly or “kits” / procedure packs	Yes	
3. TESTING ACTIVITIES	**YES**	**NO**
Analytical		No
Microbiological:		No
Sterility		No
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	Yes	

00000620MD_v1R1

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	Yes	
Bulk Pesticides, Herbicides or Rodenticides		No
Radioactive material or Radioactive medical devices	Yes	
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	Yes	
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	Yes	
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
Marceleen Cilliers	Marceleen Cilliers	Marceleen Cilliers
B Pharm and MBA	B Pharm and MBA	B Pharm and MBA

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

Name	Contact Details	Address
Ms K Naidoo (LH)	Tel: (011) 314 0140 Cell: 083 763 1419 Fax: 011 314 0141 Email: regulatory@marcusmed.co.za	Private Bag X31 Halfway House 1685
Mrs M Cilliers (AR)	Tel: (011) 314 0140 Cell: 082 774 0326 Fax: (011) 314 0141 Email: regulatory@marcusmed.co.za	63 Old Pretoria Main Road Halfway House Midrand 1685

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 sections (v1R1)

- Section 11
- Section 18.2