

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



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 Makokotfeta

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

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AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

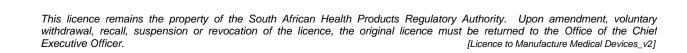
1. MANUFACTURING ACTIVITIES	YES	NO
Sterile Medical Device Manufacture (includes primary packing, but not seconda packing such as cartoning or labelling)	ry	
Single use		No
Measuring medical devices		No
Non-invasive medical device		No
Invasive medical devices		No
Active medical devices		No
Inactive medical 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	
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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
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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	

This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chiel Executive Officer. [Licence to Manufacture Medical Devices_v2]



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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





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

- o Section 11
- o Section 18.2