SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000347MD_v2R1

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 06th February 2024

This licence is granted to:

Licence Holder
Akacia Medical (Pty) Ltd
25 Harrower Road
North End
Gqeberha (Port Elizabeth)
6001

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 Semeje Makokotlela

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 22 March 2018

1ST RENEWAL DATE: 06 December 2022

EXPIRY DATE: 06 December 2027

AMENDMENT DATE: 07 February 2025

This licence remains the property of the South African Health Products Regulatory Authority [illegible] amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

ANNEXURE 1 **00000347MD_v2R1**

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	Yes	
Measuring medical devices		No
Non-invasive medical device	Yes	
Invasive medical devices	Yes	
Active medical devices		No
Inactive medical devices	Yes	
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	Yes	
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices		No

2. PACKAGING ACTIVITIES	YES	NO
Packaging of bulk product and labelling	Yes	
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly of "kits" / procedure packs	Yes	

3. TESTING ACTIVITIES	YES	NO
Analytical	Yes	
Microbiological:	Yes	
Sterility	Yes	
Stability	Yes	
Animal	Yes	
Other Testing Activities (as specified):		No

4. DISTRIBUTION ACTIVITIES	YES	NO
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class C		No
Distribution to hospitals and retail pharmacies and other clients: Class D	Yes	

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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		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		No
Import Class C medical device		No
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		No
Export Class B medical device	Yes	
Export Class C medical device		No
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
Lutho Gxakuma	Estelle Coetzee	Lutho Gxakuma
MSc. (Chemistry)	Operations management	MSc. (Chemistry)

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

Name	Contact Details	Address
Ms M. Malebatja (LH)	Tel: (041) 373 9599 Cell: 082 331 2571 Fax: (041) 373 9601 Email: maselaelo.malebatja@akaciamedical.co.za	25 Harrower Road North End Gqeberha (Port Elizabeth) Eastern Cape 6001
Mr L. Gxakuma (AR)	Tel: (041) 373 9599 Cell: 074 312 7296 Fax: (041) 373 9601 Email: lutho@akaciamedical.co.za	25 Harrower Road North End Gqeberha (Port Elizabeth) Eastern Cape 6001

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 (00000347MD_v2R1)

- Section 1.2
- Section 4.1 and 4.3
- Section 8
- Section 10
- Section 15.1 and 15.2
- Section 17.1
- Section 19, 20 and 21