SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH

Licence number: 00000403MD_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 27 January 2023.

This licence is granted to:

Licence Holder
Southern Implants (Pty) Ltd
Southern Implants Business Park
Building 1
1 Albert Road, Irene
0062

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
Boitumelo Semete-Makokotlela
16/10/2023 11:53:53(UTC+02:00)

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 22 March 2018

1ST RENEWAL DATE: 27 January 2023

EXPIRY DATE: 27 January 2028

AMENDMENT DATE: 29 September 2023

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

[Licence to Manufacture Medical Devices_v2]

ANNEXURE 1 **00000403MD_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	Yes	
Invasive medical devices	Yes	
Active medical devices		No
Inactive medical devices	Yes	
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	Yes	
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs		No

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	

5. MATERIALS HANDLED OR STORED AT THIS SITE	YES	NO
Medical devices stored at licence holder site		No
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	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
Saffy Colin	Blackbeard Graham Alan	Saffy Colin
BSC Mechanical Engineering	M.Sc Industrial Engineering	BSC Mechanical Engineering

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

Name	Contact Details	Address
Mr G A Blackbeard (LH)	Tel: 012 667 1046 Cell: 083 657 1046 Fax: 012 667 1029 Email: graham@southernimplants.com	Southern Implants Business Park Building 1,1 Albert Road Irene, 0062
Mr C Saffy (AR)	Tel: 012 667 1046 Cell: 083 294 8271 Fax: 012 667 1029 Email: colin.s@southernimplants.com	Southern Implants Business Park Building 1,1 Albert Road Irene, 0062

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 (v2)

- Section 1.2
- Section 6
- Section 19
- Section 21
- Section 23

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Southern Implants (Pty) Ltd
Southern Implants Business Park
Building 1
1 Albert Road
Irene
0062

Enquiries: Dr D Mathibe

Tel: N/A

Dear Sir/Madam,

LICENCE TO MANUFACTURE IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Licence Number 00000403MD_v2R1

Your licence to manufacture in terms of section 22C (1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document, for a medical device establishment, previously issued to you.

This licence authorises manufacturing by the licence holder; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the manufacturing of medical devices.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies, which allows it to take place other than in accordance with the licence.

This licence relates to the manufacturing of medical devices on the premises and under the supervision of the persons specified. If any change of premises or of those persons takes place, prior approval must be sought from the South African Health Products Regulatory Authority. Any proposal to make structural alterations to the premises must also be notified to the South African Health Products Regulatory Authority.

The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

Yours faithfully,

Lydia Motlogelwa

Ms Lydia Motlogela
Acting Senior Manager Medical Device Unit
Date: 12 October 2023

SAHPRA License for Manufacture 00000403MD_v2R1 (DOC-10030) Ver. 0

Approved By:

Kiara Soni - Author

January 17, 2024 1:57 PM SAST 54175c87-22de-4304-9083-6f0a3ac7ec89

Version History:

Author	Effective Date	Ver.	Status
Kiara Soni	January 17, 2024 1:57 PM SAST	0	Published