SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000028MD_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 20th of May 2022

This licence is granted to:

Licence Holder

Synthecon Sutures Manufacturing SA cc

1 Power Road

Isando, Johannesburg

1600

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: 31 July 2017

1ST RENEWAL DATE: 20 May 2022

EXPIRY DATE: 20 May 2027

AMENDMENT DATE: 03 June 2025

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 Chief Executive Officer.

ANNEXURE 1 **00000028MD_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	Yes	
Measuring medical devices		No
Non-invasive medical device		No
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		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	Yes	
Cartoning or secondary packaging	Yes	
Assembly or “kits” / procedure packs	Yes	
3. TESTING ACTIVITIES	**YES**	**NO**
Analytical	Yes	
Microbiological:		No
Sterility	Yes	
Stability	Yes	
Animal		No
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	

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		No
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		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

00000028MD_v1R1

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
Wellington Farai Mudenha	Peter Karungu	Wellington Farai Mudenha
MTech: Environmental Health	PhD: Economics	MTech: Environmental Health

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

Name	Contact Details	Address
Dr P.K Karungu (LH)	Tel: (011) 974 3220 Cell: (083) 326 7452 Fax: (011) 974 5838 Email: peter@synthecon.co.za	1 Power Road Isando, Johannesburg 1600
Mr W.F Mudenha (AR)	Tel: (011) 974 3220 Cell: (076) 235 5323 Fax: (011) 974 5838 Email: wellington@synthecon.co.za	1 Power Road Isando, Johannesburg 1600

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 4.1