SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 000000028MD_R1

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 and Exporter

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,22D 22G, 23, 26, 28, 33 and the Regulations relating to Medical Device and *In Vitro Diagnostic* Medical Devices (IVDs) 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.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 July 2017

1ST RENEWAL DATE: 20 May 2022

EXPIRY DATE: 20 May 2027

AMENDMENT DATE: N/A

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ANNEXURE 1 **000000028MD_R1**

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	YES	NO
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartooning 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		
Packaging of bulk product and labelling	Yes	
Re-labelling or redressing	Yes	
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs		No
3. TESTING ACTIVITIES		
Analytical	Yes	
Microbiological		No
Sterility	Yes	
Stability	Yes	
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
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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	YES	NO
5. MATERIALS HANDLED OR STORED AT THIS SITE		
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		
Import Class A medical device		No
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		
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

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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
WELLINGTON FARAI MUDENHA	PETER KARUNGU	WELLINGTON FARAI MUDENHA
MTECH in ENVIRONMENTAL HEALTH	PHD in ECONOMICS	MTECH in ENVIRONMENTAL HEALTH

9. PARTICULARS OF THE LICENCE HOLDER CONTACT (Other than the Authorised Representative)

Name	Contact Details	Address
Dr PK KARUNGU	Tel: 011 974 3220 Cell: 083 326 7452 Fax: 011 974 5838 Email: peter@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.
2. Once the renewed license is issued to the applicant the current existing license becomes invalid

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)