SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 00001319MD_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 25th of February 2025

This licence is granted to:

Licence Holder
Separation Scientific SA (Pty) Ltd
1480 Cranberry Street
Honeydew, Roodepoort
2170

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.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 01 April 2020

1ST RENEWAL DATE: 25 February 2025

EXPIRY DATE: 25 February 2030

AMENDMENT DATE: 24 June 2025

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ANNEXURE 1 **00001319MD_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		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	

2. PACKAGING ACTIVITIES	YES	NO
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging		No
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	

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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	Yes	
Combination medical devices with Cephalosporins	Yes	
Combination medical devices with (other) Antibiotics (as specified):	Yes	
Combination medical devices with Hormones	Yes	
Combination medical devices with Cytostatics/Cytotoxics	Yes	
Bulk Pesticides, Herbicides or Rodenticides	Yes	
Radioactive material or Radioactive medical devices	Yes	
Other potent, toxic, sensitising or hazardous materials (as specified):	Yes	
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	Yes	
Import Class B IVD	Yes	
Import Class C IVD	Yes	
Import Class D IVD	Yes	
Import RUO IVDs	Yes	
7. EXPORT	**YES**	**NO**
Export Class A medical device	Yes	
Export Class B medical device		No
Export Class C medical device		No
Export Class D medical device		No
Export Class A IVD	Yes	
Export Class B IVD	Yes	
Export Class C IVD	Yes	
Export Class D IVD	Yes	
Export RUO IVDs	Yes	

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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
Reihana Suliman	Roger Pieroni	Reihana Suliman
National Diploma (Medical Technicians - Blood Transfusion)	NHD Management Practice, NHD Elec Engi L/C Wits Technikon (Management, Electrical Service FSE)	National Diploma (Medical Technicians - Blood Transfusion)

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

Name	Contact Details	Address
Mr. G.J Northfield (LH)	Tel: 011 794 4430 Cell: 083 625 6321 Fax: N/A Email: greg@sepsci.co.za	1480 Cranberry Street Honeydew, Roodepoort 2170
Miss. R.S Suliman (AR)	Tel: 011 794 4117 / 086 173 7724 Cell: 083 625 6321 Fax: N/A Email: quality@sepsci.co.za	1480 Cranberry Street Honeydew, Roodepoort 2170

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 1.2 & 2.2
- Section 3.1
- Section 4.3 & 17.1
- Section 18.1, 18.2, 18.3, 18.4 & 18.5
- Section 19, 20 & 21

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