

# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



**Licence number: 00000651MD\_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

**Next Bioscience (Pty) Limited**

Gateway Creek, Ariane Avenue

International Gateway

Corner New Road and 6th Road

1628

### 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.

Digitally Signed by:  
Boitumelo Semete-Makokotlela  
Chief Executive Officer  
53e72d92-3391-4cd7-8da3-b6116e65c520

**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 29 June 2018**

**1<sup>ST</sup> RENEWAL DATE: 09 May 2023**

**EXPIRY DATE: 09 May 2028**

**AMENDMENT DATE: N/A**

**ANNEXURE 1**

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**AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES**

<b>1. MANUFACTURING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
<b>Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning or labelling)</b>		
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
<b>Non-sterile Manufacture</b>		
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):		
<b>Manufacture of In Vitro Devices (IVDs)</b>		
Class A IVD		No
Class B IVD		No
Class C IVD		No
Class D IVD		No
<b>End point Sterilisation of Medical Devices</b>	Yes	
<b>Manufacture of Radioactive Medical Devices</b>		No
<b>Servicing and Refurbishment of Medical Devices</b>		No
<b>2. PACKAGING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Packaging of bulk product and labelling	Yes	
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs	Yes	
<b>3. TESTING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Analytical	Yes	
Microbiological		No
Sterility		No
Stability	Yes	
Animal		No
Other Testing Activities (as specified):		No
<b>4. DISTRIBUTION ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B		No
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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<b>5. MATERIALS HANDLED OR STORED AT THIS SITE</b>	<b>YES</b>	<b>NO</b>
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):	Yes	
<b>6. IMPORT</b>	<b>YES</b>	<b>NO</b>
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
<b>7. EXPORT</b>	<b>YES</b>	<b>NO</b>
Export Class A medical device		No
Export Class B medical device		No
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
Yvonne Holt	Yvonne Holt	Rizwana Khan
MBBCH (Wits), Diploma	MBBCH (Wits), Diploma	Diploma (Biotechnology)

**9. CONTACT INFORMATION OF THE LICENCE HOLDER OR AUTHORISED REPRESENTATIVE)**

Name	Contact Details	Address
Ms. R. Khan	Tel: (011) 697 2908 Cell: 0768056557 Fax: 0116972901 Email: rizwana.x.khan@nextbio.co.za	Gateway Creek, Ariane Avenue, International Gateway Corner New Road and 6th Road 1682

**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)**