

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



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H. N. Daniels
COMMISSIONER OF OATHS
H N DANIELS
Ex Officio - MTP (SA)
28 Acacia Circle, Belhar, 7493

Licence number: 00002488MD

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 licence is granted to:

Licence Holder
Ivodont CC
Unit 14
St. Michaels Road & Howe Street
Observatory
Cape Town
7925

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: 07 October 2022

EXPIRY DATE: 07 October 2027

AMENDMENT DATE: N/A

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.
[Licence to Manufacture Medical Devices_v2]

ANNEXURE 1

00002488MD


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		
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		
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
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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	YES	NO
5. MATERIALS HANDLED OR STORED AT THIS SITE		
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		
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	Yes	
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	Yes	
Export Class B medical device	Yes	
Export Class C medical device	Yes	
Export Class D medical device	Yes	
Export Class A IVD	Yes	
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
Gary Hockly	Gary Hockly	Gary Hockly
Diploma Dental Technology	Diploma Dental Technology	Diploma Dental Technology

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

Name	Contact Details	Address
Mrs. N. Henderson	Tel: 021 448 2677 Cell: N/A Fax: N/A Email: nurith@ivodent.co.za	PO Box 140 Sea Point Cape Town 8060

10. LICENCE SPECIFIC CONDITIONS

- 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)

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Unit 14
St. Michaels Road & Howe Street
Observatory
Cape Town
7925

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 000002488MD

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 Manufacture by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the distributing 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 Manufacture 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.

Please note: The following products have not been authorised for listing in terms of the licence application to Manufacture

Yours faithfully,

Digitally Signed by:
Dimakatso Mathibe
Senior Manager: Medical devices &
Radiation Control
2b3e99b2-7995-4853-a388-d5e71a63c255

Dr Dimakatso (Theresa) Mathibe, PhD, MBL
Senior Manager Medical Device Unit

Date: 13/10/2022 03:35:31 PM

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[Signature]

COMMISSIONER OF OATHS
H N DANIELS
Ex Officio - MTP (SA)
28 Acacia Circle, Belhar, 7493

Chairperson: Prof Helen Rees • Vice-Chairperson: Dr Obakeng Khaole • Prof Joyce Tsoka-Gwegweni
Prof Patrick Demana • Dr Xolani Khayelihle Ngobese • Adv Hasina Cassim • Ms Ditaba Lucy Maraka
Mr Itani Elias Mashau • Ms Lerato Mothae • Mr Norman Baloyi • Dr Afred Kgasi • Prof Johanna Meyer
• Ms Mandisa Skhosana • Prof Yahya Choonara • Dr Zinhle Makatini
CEO: Dr Boitumelo Semete-Makokotlela