

# **SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY**



**Licence number: 00002758MD**

## **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  
**Istrodent (Pty) Ltd**  
14 Cosmic Street  
Corner Milky Street Way  
Linbro Business Park  
2090

### **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.

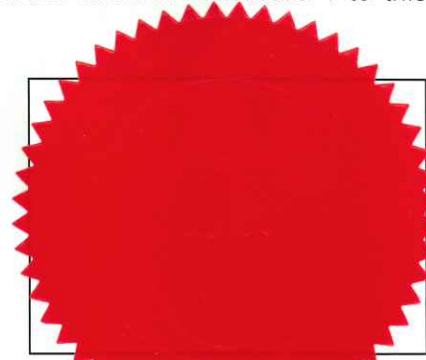
Digitally Signed by:  
Boitumelo Semete-Makokotlela  
Chief Executive Officer  
53e72d92-3391-4cd7-8da3-b611e65c520

**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 31 March 2023**

**EXPIRY DATE: 31 March 2028**

**AMENDMENT DATE: N/A**



**ANNEXURE 1**

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**AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES**

1. MANUFACTURING ACTIVITIES	YES	NO
<b>Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning or labelling)</b>		
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
<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):		No
<b>Manufacture of <i>In Vitro</i> 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>		No
<b>Manufacture of Radioactive Medical Devices</b>		No
<b>Servicing and Refurbishment of Medical Devices</b>	Yes	
<b>2. PACKAGING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging		No
Assembly or "kits" / procedure packs		No
<b>3. TESTING ACTIVITIES</b>	<b>YES</b>	<b>NO</b>
Analytical		No
Microbiological		No
Sterility		No
Stability		No
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	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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<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):		No
<b>6. IMPORT</b>	<b>YES</b>	<b>NO</b>
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		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	Yes	
Export Class B medical device	Yes	
Export Class C medical device	Yes	
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
Stephanie Leanda Hendricks	Stephanie Leanda Hendricks	Stephanie Leanda Hendricks
B-Education	B-Education	B-Education

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

Name	Contact Details	Address
Mr. S KOREN	Tel: (011) 608 1111 Cell: 082 372 2222 Fax: N/A Email: SHAUL@ISTRODENT.COM	14 Cosmic Street Corner Milky Street Way Linbro Business Park 2090

**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)**