

# **SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY**



**Licence number: 00002745MD**

## **LICENCE TO DISTRIBUTE MEDICAL DEVICES**

**In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965  
To act as a Distributor, Importer and Exporter**

This licence is granted to:

Licence Holder  
**Confi-Dent Clinical CC**  
28, 2nd Street Orange Grove  
Johannesburg  
Gauteng  
2192

### **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 3 pages.**

This facility is authorised to perform the 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: 24 March 2023**

**EXPIRY DATE: 24 March 2028**

**AMENDMENT DATE: N/A**

**ANNEXURE 1**

**AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES**

<b>1. 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		NO
<b>2. MATERIALS HANDLED OR STORED AT THIS SITE</b>	<b>YES</b>	<b>NO</b>
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>3. 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		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>4. 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		NO
Export Class A IVD		NO
Export Class B IVD		NO
Export Class C IVD		NO
Export Class D IVD		NO
Export RUO IVDs		NO

**5. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER**

<b>Authorised Representative</b>	<b>Manufacture / Import / Distribution / Export Control Person</b>	<b>Quality Control Person</b>
Ricardo Faria	Noelene Weightman	Noelene Weightman
B. Tech: Chemical Engineering	N/A	N/A

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

<b>Name</b>	<b>Contact Details</b>	<b>Address</b>
Mrs N Weightman	Tel: 011 483 1881 Cell: 083 260 9311 Fax: 011 483 1882 Email: <a href="mailto:weightman@confi-dent.co.za">weightman@confi-dent.co.za</a>	28 2nd Street Orange Grove Johannesburg 2192

**7. 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.

**8. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)**