SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH

Licence number: 00000303MD_v1R1

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 amended licence replaces the licence issued on the 10th of February 2023

This licence is granted to:

Licence Holder

Megadent CC

12 Valmar Road, Vygeboom

Durbanville

Cape Town

7550

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.

Boitumelo Semete-Makokotlela

Boitumelo Semete-Makokotlela

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 22 March 2018

1ST RENEWAL DATE: 10 February 2023

EXPIRY DATE: 10 February 2028

AMENDMENT DATE: 08 October 2024

This licence remains the property of the South African Health Products Regulatory Authority and in the event of voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

ANNEXURE 1 **00000303MD_v1R1**

AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES

1. 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		No
Distribution to hospitals and retail pharmacies and other clients: Class D		No
2. MATERIALS HANDLED OR STORED AT THIS SITE	**YES**	**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
3. IMPORT	**YES**	**NO**
Import Class A medical device	Yes	
Import Class B medical device	Yes	
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
4. EXPORT	**YES**	**NO**
Export Class A medical device	Yes	
Export Class B medical device	Yes	
Export Class C medical device		No
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

Authorised Representative	Manufacture / Import / Distribution / Export Control Person	Quality Control Person
Wayne Gleeson	Ralf Schulz	Ralf Schulz
Matric	Matric	Matric

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

Name	Contact Details	Address
Mr R. Schulz (LH)	Tel: 021 552 2721 Cell: 082 567 9286 Fax: 021 551 5311 Email: ralf@megadent.co.za	12 Valmar Road, Vygeboom Durbanville Cape Town 7550
Mr W. Gleeson (AR)	Tel: 021 552 2721 Cell: 084 629 8383 Fax: 021 551 5311 Email: wayne@megadent.co.za	12 Valmar Road, Vygeboom Durbanville Cape Town 7550

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)

See amended sections (v1R1)

- Section 1.2 & 2.2
- Section 16 & 19.4