SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001598MD

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

ONE EIGHT INNOVATION (PTY) LTD

80 Greenlands Crescent
Sunningdale
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.

DocuSigned by:
Boitumelo Semete-Makokotlela

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 06 October 2020

EXPIRY DATE: 06 October 2025

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.

ANNEXURE 1 ***00001598MD***

AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES

1. DISTRIBUTION ACTIVITIES	YES	NO
Distribution to hospitals and retail pharmacies and other clients: Class A		No
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		
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		
Import Class A medical device		No
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		
Export Class A medical device		No
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

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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
Moshe Lichtenstein	Moshe Lichtenstein	Moshe Lichtenstein
Biomedical Health Science Degree	Biomedical Health Science Degree	Biomedical Health Science Degree

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

Name	Contact Details	Address
M Lichtenstein	Tel: N/A Cell: 826949696 Fax:011 882-2506 Email: ml@one8innovation.com	80 Greenlands Crescent Sunningdale Johannesburg, Gauteng 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)