

# **SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY**



**Licence number: 00003656MD**

## **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 Exported**

This licence is granted to:

Licence Holder

**Stat Tiakeni Medical (Pty) Ltd**

227 Main Avenue

Ferndale

Randburg

2194

### **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 Seemole Makoketela

**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 10 May 2024**

**EXPIRY DATE: 10 May 2029**

**AMENDMENT DATE: N/A**

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



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Bathumelo Semeto-Makoketela  
A handwritten signature in blue ink, reading 'Bathumelo Semeto-Makoketela'.

**CHIEF EXECUTIVE OFFICER**

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**ANNEXURE 1**

**00003656MD**

**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	Yes	
<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): Batteries - Various	Yes	
<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	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>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	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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## 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
Paul Anton Fourie	Bruce William Poynton	Leon Swanepoel
NTC 6 (Light current electronics)	B. Comm (Financial Management, Accounting and Taxation)	NSC (Clinical engineering, medical sales and marketing)

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

Name	Contact Details	Address
Mr S. J. McDonnell (LH)	Tel: (011) 708 6363 Cell: (083) 632 1061 Fax: (011) 708 6364 Email: <a href="mailto:simon@statmedical.co.za">simon@statmedical.co.za</a>	227 Main Avenue Ferndale Randburg 2194
Mr P. A. Fourie (AR)	Tel: (011) 708 6363 Cell: (083) 600 3740 Fax: (011) 708 6364 Email: <a href="mailto:paul@statmedical.co.za">paul@statmedical.co.za</a>	227 Main Avenue Ferndale Randburg 2194

## 7. 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.

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