

# **SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY**



**Licence number: 00000970MD**

## **LICENCE TO WHOLESALE MEDICAL DEVICES**

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

This licence is granted to:

**Licence Holder**

**1 Stop Medical Supplies cc**

**Unit 14, 997 Richards Drive**

**Halfway House, Midrand**

**Johannesburg**

**Gauteng**

**1685**

### **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 product 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.

  
**ACTING CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 31 May 2019**

**EXPIRY DATE: 31 May 2024**

**AMENDMENT DATE: N/A**



## ANNEXURE 1

00000970MD

<b>AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES</b>
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<b>1. SPECIFIC ACTIVITIES</b>					<b>YES</b>	<b>NO</b>
Locally procured medical devices are stored and handled at this site					Yes	
"Special" manufactured products are handled at this site						No
Medical devices are exported from this site on behalf of SAHPRA licensed manufacturers or distributors of medical devices						No
<b>2. METHOD OF ONWARD DISPATCH</b>					<b>YES</b>	<b>NO</b>
Post						No
Courier / Van Service					Yes	
Own Courier / Van Service					Yes	
Customer Collection					Yes	
Other (as specified):						No
<b>3. CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE</b>						
Class Medical Device		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>RUO</b>
Type Medical Device						
Measuring Medical Device						
Blood storage / transportation product						
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min	X	X			
	> 60 min & < 30 days	X	X	X		
	>30 days					
Inactive Medical Device		X	X	X		
Active Medical Device		X	X			
Contraceptive						
Combination Medical Device						
IVD			X	X		
<b>4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE</b>					<b>YES</b>	<b>NO</b>
Licence to manufacture / distribute medical devices (as specified): Manufacture (00000641MD)					Yes	
Licence to manufacture / wholesale medicine (as specified):						No
<b>5. SITE LISTING ON A SAHPRA LICENCE HELD BY ANOTHER LICENCE HOLDER</b>					<b>YES</b>	<b>NO</b>
Medical Device Establishment Licence to Manufacture						No
Medical Device Establishment Licence to Distribute						No



**00000970MD****6. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER**

<b>Authorised Representative</b>
Rajen Chetty
Dip. Business Management
MBA

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

<b>Name</b>	<b>Contact Details</b>	<b>Address</b>
F Chetty	Tel: 076 053 8647 Fax: 086 224 9552 Email: fiona@1stopmedical.co.za	Unit 14, 997 Richards Drive Halfway House, Midrand Johannesburg Gauteng 1685

**8. 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.

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