SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001211MD_v1

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 and Importer

This amended licence replaces the licence issued on the 19th of September 2019

This licence is granted to:

Licence Holder
V-Tech (Pty) Ltd
Corner of Douglas and Old Pretoria Roads
V-Tech Building 2
Midrand
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 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.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 19 September 2019

EXPIRY DATE: 19 September 2024

AMENDMENT DATE: 10 June 2022

ANNEXURE 1 **00001211MD_v1**

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		No
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
Johan Oosthuysen	Dale Parrish	Michael Henn
BVSc, MBL	DipVetNurs, MBA	Bpharm

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

Name	Contact Details	Address
D Parrish	Tel: Cell: 087 150 5925 Fax: N/A Email: dale@v-tech.co.za	Private Bag X25 Halfway House Midrand 1685

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 Section/s (v1):

- Section 4.3

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

V-Tech (Pty) Ltd
Corner of Douglas and Old Pretoria Roads
V-Tech Building 2
Midrand
1685

Enquiries: Dr D Mathibe
Tel: N/A

Dear Sir/Madam,

LICENCE TO DISTRIBUTE IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Licence Number 00001211MD_v1

Your licence to distribute in terms of section 22C(1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document, for a medical device establishment, previously issued to you.

This licence authorises distribute by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the distributing of medical devices.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies, which allows it to take place other than in accordance with the licence.

This licence relates to the distribute of medical devices on the premises and under the supervision of the persons specified. If any change of premises or of those persons takes place, prior approval must be sought from the South African Health Products Regulatory Authority. Any proposal to make structural alterations to the premises must also be notified to the South African Health Products Regulatory Authority.

The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

Yours faithfully,

Dr Dimakatso (Theresa) Mathibe, PhD, MBL
Senior Manager Medical Device Unit
Date: 19/06/2022