# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

**Licence number: 00000676MD**

# LICENCE TO MANUFACTURE MEDICAL DEVICES

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

This licence is granted to:

Licence Holder
**Medi-Clave (Pty) Ltd**
Portion 69, Melvic
Schurveberg Ext 488
Pretoria
0001

**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 4 pages.**

This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

**ACTING CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 28 September 2018**

**EXPIRY DATE: 28 September 2023**

**AMENDMENT DATE: N/A**

**ANNEXURE 1** ***00000676MD***

## AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

| 1. MANUFACTURING ACTIVITIES | YES | NO |
|---|---|---|
| **Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning or labelling)** | | |
| Single use | | No |
| Measuring medical devices | | No |
| Non-invasive medical device | | No |
| Invasive medical devices | | No |
| Active medical devices | | No |
| Inactive medical devices | | No |
| Contraceptive medical devices | | No |
| Combination medical devices | | No |
| Other sterile medical devices (as specified): | | No |
| **Non-sterile Manufacture** | | |
| Measuring medical devices | | No |
| Non-invasive medical devices | | No |
| Invasive medical devices | | No |
| Active medical devices | Yes | |
| Inactive medical devices | | No |
| Contraceptive medical devices | | No |
| Combination medical devices | | No |
| Other non-sterile medical devices (as specified): | | No |
| **Manufacture of *In Vitro* Devices (IVDs)** | | |
| Class A IVD | | No |
| Class B IVD | | No |
| Class C IVD | | No |
| Class D IVD | | No |
| **End point Sterilisation of Medical Devices** | Yes | |
| **Manufacture of Radioactive Medical Devices** | | No |
| **Servicing and Refurbishment of Medical Devices** | Yes | |
| | | |
| **2. PACKAGING ACTIVITIES** | | |
| Packaging of bulk product and labelling | | No |
| Re-labelling or redressing | Yes | |
| Cartoning or secondary packaging | Yes | |
| Assembly or "kits" / procedure packs | | No |
| | | |
| **3. TESTING ACTIVITIES** | | |
| Analytical | | No |
| Microbiological | | No |
| Sterility | Yes | |
| Stability | | No |
| Animal | | No |
| Other Testing Activities (as specified): | | No |
| | | |
| **4. DISTRIBUTION ACTIVITIES** | | |
| 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 | | No |

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| | YES | NO |
|---|---|---|
| **5. MATERIALS HANDLED OR STORED AT THIS SITE** | | |
| Medical devices stored at licence holder site | Yes | |
| 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 |
| | | |
| **6. IMPORT** | | |
| Import Class A medical device | Yes | |
| Import Class B medical device | Yes | |
| Import Class C medical device | Yes | |
| 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 |
| | | |
| **7. EXPORT** | | |
| Export Class A medical device | Yes | |
| Export Class B medical device | Yes | |
| Export Class C medical device | Yes | |
| 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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## 8. 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 |
|---|---|---|
| Johannes Henning Jacobus Rossouw | Johann Bosman Hoffman | Johannes Henning Jacobus Rossouw |
| Certificate : Steam Utilisation | N5: Engineering | Certificate : Steam Utilisation |

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

| Name | Contact Details | Address |
|---|---|---|
| Mr. J. Bezuidenhout | Tel: 012 379 1983<br>Cell: 082 569 8731<br>Fax: 086 551 6700<br>Email: johannbez@medi-clave.co.za | P. O Box 1652<br>Hartbeespoort<br>0216 |

## 10. 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.

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

# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Republic of South Africa
Private Bag X828
PRETORIA
0001

DEPARTMENT OF HEALTH
Republic of South Africa

Republiek van Suid-Afrika
Privaatsak X828
PRETORIA
0001

Medi-Clave (Pty) Ltd
Portion 69, Melvic
Schurveberg Ext 488
Pretoria
0001

Dear Sir/Madam,

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

Licence Number 00000676MD

Your licence to manufacture 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 manufacture 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 manufacture 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 manufacture 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 power to revoke, suspend or amend licences in terms of section 22E.

Yours faithfully,

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**ACTING CHIEF EXECUTIVE OFFICER**

Date: 28 September 2018

Navrae/Enquiries: Ms A.A Keyter Telefoon/Telephone: (012) 395 9473 /9262 /9171