# MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH

MEDICINES CONTROL COUNCIL

**Licence number: 00000186MD**

## 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
**Obsidian Health (Pty) Ltd**
Malibongwe Drive
Randburg
Gauteng
2188

**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, 22G, 22H, 23, 26, 28, 33 and the Regulations relating to Medical Device and *In Vitro Diagnostic* Medical Devices (IVDs) 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant Medicines Control Council Guidelines.

**This licence consists of 4 pages.**

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

**REGISTRAR OF MEDICINES**

**ORIGINAL DATE OF ISSUE: 27 November 2017**

**EXPIRY DATE: 27 November 2022**

**AMENDMENT DATE: N/A**

*This licence remains the property of the National Department of Health and the Medicines Control Council. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Registrar.*

**ANNEXURE 1** ***00000186MD***

## AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

| **1. MANUFACTURING ACTIVITIES** | YES | NO |
|---|---|---|
| **Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartooning or labelling)** | | |
| Single use | Yes | |
| Measuring medical devices | Yes | |
| Non-invasive medical device | Yes | |
| Invasive medical devices | Yes | |
| 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 | Yes | |
| Non-invasive medical devices | Yes | |
| Invasive medical devices | Yes | |
| Active medical devices | | No |
| 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 | Yes | |
| Re-labelling or redressing | Yes | |
| Cartoning or secondary packaging | Yes | |
| Assembly or "kits" / procedure packs | | No |
| | | |
| **3. TESTING ACTIVITIES** | | |
| Analytical | | No |
| Microbiological | | No |
| Sterility | | No |
| Stability | | No |
| Animal | | No |
| Other Testing Activities (as specified): | | No |
| | | 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 | Yes | |

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| | | |
|---|---|---|
| **5. MATERIALS HANDLED OR STORED AT THIS SITE** | | No |
| 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 | Yes | |
| Import Class A IVD | Yes | |
| Import Class B IVD | Yes | |
| 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 | Yes | |
| Export Class A IVD | Yes | |
| Export Class B IVD | Yes | |
| 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 |
|---|---|---|
| Dennis Beech | Landman Shawn | Dennis Beech |
| Read in B.Com (Transport Economics) | B. Com & B. Acc + CA (SA) | Read in B.Com (Transport Economics) |

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

| Name | Contact Details | Address |
|---|---|---|
| Mr. S. Landman | Tel: 087 357 5901<br>Cell:082 411 5834<br>Fax:086 687 5384<br>Email:shawnl@obsidianhealth.co.za | PO Box 3145<br>Northriding<br>Gauteng<br>2162 |

## 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)

**MEDICINES CONTROL COUNCIL**
**MEDISYNEBEHEERRAAD**

Republic of South Africa
Private Bag X828
PRETORIA
0001

DEPARTMENT OF HEALTH
Republic of South Africa

**IKANSELE ELAWULA**
**UKUSETSHENISWA KWEMITHI**
**KHANSELE TAOLO YA DIHLARE**

Republiek van Suid-Afrika
Privaatsak X828
PRETORIA
0001

Obsidian Health (Pty) Ltd
Cosmo Business Park
Malibongwe Drive
Randburg
Gauteng
2188

Dear Sir/Madam,

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

Licence Number 00000186MD

Your licence to manufacture, import, export and 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 manufacture, import, export and distribution 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, import, export and distribution 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, import, export and distribution 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 Medicines Control Council. Any proposal to make structural alterations to the premises must also be notified to the Medicines Control Council.

The Medicines Control Council has power to revoke, suspend or amend licences in terms of section 22E.

Yours faithfully,

**REGISTRAR OF MEDICINES**
Date: 27 November 2017