

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00004159MD

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 Exporter

This licence is granted to:

Licence Holder
The Cleaning Company
18 Vegkop Street
Noordheuwel
Krugerdomp
1739

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.

Boitumeto Senete Makokotela

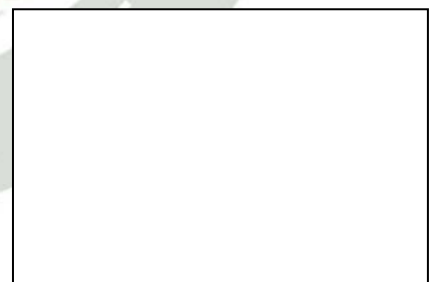
SAHPRA

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 12 November 2024

EXPIRY DATE: 12 November 2029

AMENDMENT DATE: N/A



This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

ANNEXURE 1

00004159MD

| |
|---|
| AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES |
|---|

| 1. DISTRIBUTION ACTIVITIES | YES | NO |
|--|------------|-----------|
| 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 | |
| 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 | 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 |
| 4. 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 | | 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 |
|------------------------------------|---|------------------------------------|
| Mahlatse Matthews Mokone | Mahlatse Matthews Mokone | Mahlatse Matthews Mokone |
| Diploma in Business Administration | Diploma in Business Administration | Diploma in Business Administration |

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

| Name | Contact Details | Address |
|---------------------------|---|---|
| Mr M. M Mokone (LH/AR) | Tel: (071)1668860 Cell: (071)1668860 Fax: N/A Email: info@eyeconafrika.co.za | 18 Vegkop Street Noordheuwel Krugerdp 1739 |

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)

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