SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001177MD_R1

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
Axim (Pty) Ltd
63 Old Pretoria Main Road
Halfway House
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 4 pages.

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

Boitumelo Semete-Makokotlela
Boitumelo Semete-Makokotlela
SIGNIFLOW

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 23 August 2019

1ST RENEWAL DATE: 26 April 2024

EXPIRY DATE: 26 April 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 **00001177MD_R1**

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		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)		No
Class A IVD		No
Class B IVD		No
Class C IVD		No
Class D IVD		No
End point Sterilisation of Medical Devices		No
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices	Yes	
2. PACKAGING ACTIVITIES	**YES**	**NO**
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly or “kits” / procedure packs		No
3. TESTING ACTIVITIES	**YES**	**NO**
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified):		No
4. 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	

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5. MATERIALS HANDLED OR STORED AT THIS SITE	YES	NO
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	Yes	
Bulk Pesticides, Herbicides or Rodenticides		No
Radioactive material or Radioactive medical devices	Yes	
Other potent, toxic, sensitising or hazardous materials (as specified):		No
6. IMPORT	**YES**	**NO**
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	Yes	
Import RUO IVDs		No
7. EXPORT	**YES**	**NO**
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

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
Brett Anthony Edwards	Brett Anthony Edwards	Luciana Teresa Calha
National Diploma S4 Electrical Engineering	National Diploma S4 Electrical Engineering	Business Administration & Management

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

Name	Contact Details	Address
Mrs L T Calha (LH)	Tel: 031 489 9400 Cell: 083 320 4148 Fax: 031 463 3440 Email: regulatoryaxim@axim.co.za	Private Bag X169 Halfway House 1685
Mr B Edwards (AR)	Tel: 011 314 0140 Cell: 082 771 7400 Fax: 011 314 0141 Email: regulatoryaxim@axim.co.za	63 Old Pretoria Main Road Halfway House Midrand 1685

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.
2. Once the renewed license is issued to the applicant the current existing license becomes invalid.

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

1. Only the following unregistered medical device or IVD, listed below, has been granted authorisation for sale in terms of Section 21 of Act 101 of 1965.
2. Any medical device or IVD sold in pursuance of any authority granted under Section 21(1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

3. Distribution is limited to the conditions prescribed in the Section 21 Authorisation and in line with the National Department of Health Testing Strategy and the National Department of Health Clinical Guideline, only.
4. Regulation 21(1) (a) of the Regulations Relating to Medical Devices and In vitro Diagnostics be followed, A Class C and Class D medical device/IVD may be advertised to Healthcare professionals only

PRODUCT NAME	PRODUCT DESCRIPTION	ORIGINAL MANUFACTURER	STATUS
Magabio plus Virus Nucleic Acid Purification Kit	Molecular	Hangzhou Bioer Technology Co., Ltd. 1192 Bin An Rd., Binjiang District,Hangzhou City,Zhejiang Proinvince, 310053, China	Listing Authorised 11/06/2020
Biospin Virus Nucleic acid Extraction Kit	Molecular	Hangzhou Bioer Technology Co., Ltd. 1192 Bin An Rd., Binjiang District,Hangzhou City,Zhejiang Proinvince, 310053, China	Listing Authorised 11/06/2020
MAGLUMI® SARS-CoV-2 S-RBD IgG II assay	Antibody test (Professional)	Shenzhen New Industries Biomedical Engineering Co., Ltd	Listing Authorised 13/06/2023 Section 21 Authorisation MD21.202306/02