MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

Licence number: 00000220MD

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

Burnshield (Pty) Ltd

1 Manchester Road, Block 3

Wadeville

Germiston

1422

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 ***00000220MD***

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		No
Non-invasive medical device		No
Invasive medical devices	Yes	
Active medical devices		No
Inactive medical devices	Yes	
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	Yes	
Invasive medical devices		No
Active medical devices		No
Inactive medical devices	Yes	
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		No
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices		No
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	Yes	
3. TESTING ACTIVITIES		
Analytical	Yes	
Microbiological		No
Sterility		No
Stability	Yes	
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B		No
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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5. 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
6. IMPORT		
Import Class A medical device		No
Import Class B medical device		No
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		No
Export Class B medical device		No
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
Sheryl Protheroe	Massimo Di Domencio	Sheryl Protheroe
BSc (hons) Microbiology and Biotechnology	BSc (hons) Medical Biochemistry	BSc (hons) Microbiology and Biotechnology

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

Name	Contact Details	Address
Mr. M. Di Domenico	Tel: 011 827 4140 Cell: 082 881 2074 Fax: 011 827 9009 Email: max@burnshield.com	PO Box 14737 Wadeville Germiston 1422

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

Burnshield (Pty) Ltd
1 Manchester Road, Block 3
Wadeville
Germiston
1422

Dear Sir/Madam,

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

Licence Number 00000220MD

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

Faks/Fax: (012) 395 9201 Telefoon/Telephone: (012) 395 8032 Navrae/Enquiries: Dr JC Gouws