

MEDICINES CONTROL COUNCIL



Licence Number: 0000000345

LICENCE TO MANUFACTURE MEDICINES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
Air Liquide (Pty) Ltd - Alrode
Cnr Vereeniging & Andre Marais Street, Alrode , Gauteng , 1451

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 medicines manufactured in this facility, 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, 33, Regulations 8, 9, 10, 12, 13, 37, 40, 43, 44, 45, 48 and all relevant Medicines Control Council Guidelines.

This facility is authorized to perform the manufacturing activities depicted in Annexure 1 to this licence.

REGISTRAR OF MEDICINES

ISSUE DATE: 19 October 2015

EXPIRY DATE: 19 October 2020



AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES		
1.MANUFACTURING ACTIVITIES	YES	NO
Sterile, Non-Biological Manufacture(includes filling, but not cartoning or labelling)		
Large volume parenteral products		NO
Small volume parenteral products		NO
Other sterile dosage forms: -		NO
Non-Sterile Manufacture		
Tablets		NO
Capsules		NO
Liquids		NO
Semi-solids		NO
Suppositories		NO
Other non-sterile dosage forms: -		NO
Biological Manufacture		
Vaccines		NO
Sera and other immunologicals		NO
Blood and other blood products		NO
Other biological products: -		NO
Medical Gas Manufacture	YES	
Radioactive Medicines Manufacture		NO
Complementary Medicines Manufacture		NO
2.PACKAGING ACTIVITIES		
Packaging of bulk product and labelling	YES	
Re-labelling or redressing		NO
Cartoning or secondary packaging	YES	
3.TESTING ACTIVITIES		
Analytical	YES	
Microbiological		NO
Sterility		NO
Stability		NO
Animal		NO
Other Testing Activities: false		NO
Other Testing Activities Details: -		
4.DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies	YES	
Fine distribution to retail pharmacies and others	YES	
5.MATERIALS HANDLED OR STORED AT THIS SITE		
Penicillins		NO
Cephlosporins		NO
Hormones		NO
Cytostatics/Cytotoxics		NO
Bulk Pesticides, Herbicides or Rodenticides		NO
Potent Steroids		NO
Other potent, toxic, sensitising or hazardous materials : -		NO
6. IMPORT		NO
7. EXPORT	YES	
Specific Products Exported: -		

**MEDICINES CONTROL COUNCIL
MEDISYNEBEHEERRAAD**

Republic of South Africa
Private Bag X828
PRETORIA

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DEPARTMENT OF HEALTH
Republic of South Africa

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

Republiek van Suid-Afrika
Privaat Sak X828
PRETORIA

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Air Liquide (Pty) Ltd - Alrode

P O Box 124200
Alrode
Gauteng
1451

Dear Sir/Madam,

RE: LICENCE TO ACT AS **Manufacturer and Exporter** IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965.

Manufacturer and Exporter Licence *0000000345.-.16*

Your licence to act as **Manufacturer and Exporter** 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 previously issued to you.

This licence authorises the acting as **Manufacturer and Exporter** 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 acting as a **Manufacturer and Exporter** of products.

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 acting as **Manufacturer and Exporter** of products on the premises and under the supervision of the persons specified. If any change of premises or of those persons take place, prior approval must be sought from the Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

The Licensing Authority has power to revoke licences in terms of sections 22C.

Yours faithfully,

PP

REGISTRAR OF MEDICINES

DATE: *19/10/2015*

Faks/Fax: (012) 312 3105

Navrae/Enquiry: Dr JC Gouws

Telefoon/Telephone: (012) 312 0018