

DEBx Africa (Pty) Ltd

21 Oak Avenue
Kenilworth
Cape Town
Western Cape
7708

Enquiries: Ms M Omarjee
Tel: N/A

Dear Sir/Madam,

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

Licence Number 00001910MD

Your licence to manufacture 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 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 manufacturing 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 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 South African Health Products Regulatory Authority. Any proposal to make structural alterations to the premises must also be notified to the South African Health Products Regulatory Authority.

The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

Yours faithfully,

DocuSigned by:



Ms Momeena Omarjee

Acting Deputy Director Medical Devices

Date: 20 April 2021