

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000028MD_v1R1

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 amended licence replaces the licence issued on the 20th of May 2022

This licence is granted to:

Licence Holder
Synthecon Sutures Manufacturing SA cc
1 Power Road
Isando, Johannesburg
1600

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.

Bontumelo Semete-Makokotela
A handwritten signature in blue ink, reading 'Bontumelo Semete-Makokotela', is written over a white rectangular box. Below the signature is a small blue logo with the text 'eSonicFlow'.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 July 2017

1ST RENEWAL DATE: 20 May 2022

EXPIRY DATE: 20 May 2027

AMENDMENT DATE: 03 June 2025

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.