

# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000144MD\_v1

## 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 and Importer

This amended licence replaces the licence issued on the 27<sup>th</sup> November 2017

This licence is granted to:

Licence Holder  
**Werkomed (Pty) Ltd**  
Unit A1, 5 Galaxy Avenue  
Linbro Business Park  
Johannesburg  
2065

### 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.

  
ACTING CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 27 November 2017

EXPIRY DATE: 27 November 2022

AMENDMENT DATE: 22 March 2018

