

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001194MD

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 licence is granted to:

Licence Holder

Quantzmed Personal Health (Pty) Ltd t/a Quantumed

Unit 4, Acacia Industrial Park

17 Arbeid Ave

Strydompark

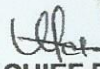
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On the following terms and conditions:

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: 19 September 2019

EXPIRY DATE: 19 September 2024

AMENDMENT DATE: N/A

This licence remains the property of the National Department of Health and the Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence must be returned to the Office of the Chief Executive Officer. [Licence to Manufacture Medical Devices_v3]

