



Certificate of Registration

This is to certify that the Quality Management System for Medical Devices of

M and L Medical Suppliers CC T/A VIVA Medical

Unit 3 On Delson Park, Somerset Business Park, Somerset West, Cape Town, Western Cape

Has been assessed and found to satisfy the requirements of

ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

in respect of

Manufacture and Distribution of Disposable Infusion Sets, Disposable Light-resistant Infusion Sets, Disposable Burette Infusion Sets. Disposable Blood Transfusion Sets, Disposable Extension Tubes and Disposable Needle Free Connectors.

EXCLUDING CLAUSES:

None

NON-APPLICABLE CLAUSES:

Clause 7.5.3 Installation activities Clause 7.5.4 Servicing activities

Clause 7.5.5 Particular requirements for sterile medical devices

Clause 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

Clause 7.5.9.2 Particular requirements for implantable medical devices

Clause 8.3.4 Rework

This certificate, including the schedule which forms an integral part thereof:

- Is issued without alteration;
- Is identified by the applicable registration number;
- Is subjected to any condition or limitation contained therein;
- Is valid subject to ongoing compliance with certification requirements;
- Bears the embossed SACAS seal. In absence of the seal, the certificate and the schedule shall be invalid.
- The certificate stays the property of SACAS.
- SACAS web-site to be verified ensuring certificate is valid. (www.sacas.co.za)

Registration Number

QMSMED00017-2

Effective Date

22 April 2025

Expiry Date

21 April 2028

Date of Original Registration

22 April 2022

Managing Director









SACAS SA Unit 14 Prime Business Park Nr 6 Rabie Street CE 6 Vanderbijlpark PO Box 1290 Vanderbijlpark

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