

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

Medical Innovations (Pty) Ltd. 7 Cyclonite Street, The Interchange, Somerset West, Western Cape, 7129

Has been assessed and found to satisfy the requirements of

ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

in respect of

Import and distribution of health care products including needles, syringes, catheters, wound dressings, surgical instruments and accessories, as well as the manufacture, installation and servicing of hospital equipment including pendants, pedestals, theatre control panels, bed service panels and trolleys.

EXCLUDING/NON-APPLICABLE CLAUSES:

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

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. (<u>www.sacas.co.za</u>)

Registration Number

Effective Date

Expiry Date

Date of Original Registration

Managing Director

ISO

16 ST COLUMN AREAN OF MULTILATION

QMSMED00013-1 06 March 2025

01 November 2027

02 November 2021

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SACAS SA Unit 14 Prime Business Park Nr 6 Rabie Street CE 6 Vanderbijlpark PO Box 1290 Vanderbijlpark 1900

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