



Certificate of Registration

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

**Medical Innovations (Pty) Ltd.
SOMERSET WEST**

*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.

NON-APPLICABLE CLAUSES:

- Clause 7.5.5 Particular requirements for sterile medical devices
- Clause 7.5.6 Validation of processes for production and service
- 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. (www.sacas.co.za)

Registration Number

QMSMED00013

Effective Date

02 November 2021


Expiry Date

01 November 2024

Date of Original Registration

02 November 2021

Managing Director



SACAS



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