



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



Certificate of Registration

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

Medi-Clave (Pty) Ltd. PRETORIA

Has been assessed and found to satisfy the requirements of

ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

in respect of

The design and development, manufacturing, distribution, installation and servicing of a variety of autoclaves. The importation and wholesaling of related products and consumables.

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 system

Clause 7.5.9.2 Particular requirements for implantable medical device

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

QMSMED00016

Effective Date

18 March 2022

Expiry Date

17 March 2025

Date of Original Registration

18 March 2022

Managing Director



