



Certificate of Registration

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

**Shonaquip (Pty) Ltd.
CAPE TOWN**

*Has been assessed and found
to satisfy the requirements of*

**ISO 13485:2016
QUALITY MANAGEMENT SYSTEMS
FOR MEDICAL DEVICES**

in respect of

***The design, prescription, manufacture and provision of standard, modular
and customized mobility and 24-hour posture support devices, and related
therapy equipment.***

EXCLUDING CLAUSES:
None

NON-APPLICABLE CLAUSES:
Clause 7.5.3 Installation activities Installation and verification
Clause 7.5.4 Servicing activities Servicing
Clause 7.5.5 Particular requirements for sterile medical devices Sterilization
Clause 7.5.6 Validation of processes for production and service provision Validation
Clause 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems
Clause 7.5.9.2 Traceability 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 **QMSMED00018**

Effective Date **13 May 2022**

Expiry Date **12 May 2025**

Date of Original Registration **13 May 2022**

Managing Director



C 59h

SACAS



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