



Certificate of Registration

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

EREZ Labmed (Pty) Ltd.
**5 Kyalami Village, 57 Forssman Close, Barbeque
Downs, Midrand, Gauteng, 1684**

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

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

in respect of

***The distribution of In-Vitro Diagnostic (IVD) devices,
including laboratory consumables and equipment.***

EXCLUDING/NON-APPLICABLE CLAUSES:

- Clause 7.3 Design and development
- Clause 7.5.3 Installation activities
- Clause 7.5.4 Servicing activities
- Clause 7.5.6 Validation of processes for production and service provision
- 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
- 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 website to be verified ensuring certificate is valid. (www.sacas.co.za)

Registration Number

QMSMED00057

Effective Date

18 February 2025

Expiry Date

09 October 2025

Date of Original Registration

10 October 2022

Managing Director





C 59h



SACAS



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