

Business Park Nr 6 Rabie Street CE 6 Vanderbijlpark PO Box 1290 Vanderbijlpark 1900



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

Southern Trials (Pty) LTD t/a Fisher Clinical Services

36 Parkview Street, Highway Business Park, Centurion, Rooihuiskraal, Pretoria, Gauteng

> Has been assessed and found to satisfy the requirements of

ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

in respect of

Manufacturing (labelling and kit packing), warehousing, distribution, import and/or export of Medical devices or IVD's on behalf of the sponsor to support their clinical trials.

> EXCLUDING CLAUSES: Clause 7.3 Design and development

NON-APPLICABLE CLAUSES: Clause 7.5.3, 7.5.4, 7.5.5, 7.5.7 & 7.5.9.2

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

QMSMED00034

Effective Date

Managing Director

29 May 2027

30 May 2024

Expiry Date

Date of Original Registration

30 May 2024



