Certificate ES19/85502

The quality management system of

Xavant Technology (Pty) Ltd

Unit 102 Tannery Industrial Park, 309 Derdepoort Road, Silverton, Pretoria, 0184, South Africa
Facility number: F001074

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Canada: Medical Device Regulations SOR/98-282, Part 1
Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities
The design, development, manufacture, servicing, and distribution of neuromuscular stimulator, for peripheral nerve location and neuromuscular blocking agent monitoring during regional and general anaesthesia, and neuromuscular stimulators for use in somatic and neuropathic pain management, including home use and point of care. Servicing of radiofrequency ablation generators.

This certificate is valid from Effective date 2025-02-17 until Expiry date 2028-02-17 and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 2019-02-20

L. Henderson

Authorised by
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.