Certificate US19/819943249

The quality management system of

MedOne Surgical, Inc.

670 Tallevast Road, Sarasota, FL 34243, United States of America
Facility number: F002900

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 Devices Regulations (SOR/98-282) Part 1 - General
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021); Japan PMD Act (as applicable)
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
Design, manufacture and distribution of sterile Ophthalmic devices: Cannulae, knives, forceps, brushes, tubing, picks, backflush devices, injections kits, and ophthalmic instruments for ophthalmic surgery.

This certificate is valid from Effective date 2025-04-11 until Expiry date 2028-04-11 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 2019-07-02

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.