EU Quality Management System Certificate US25/00000348

The management system of

MedOne Surgical, Inc.

670 Tallevast Road, Sarasota, FL 34243, United States Of America
SRN Number: US-MF-000002763

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 01 September 2025 until 01 September 2030 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 01 March 2030

Issue 1. Certified since 01 September 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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MedOne Surgical, Inc.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa device

MDN1206, MDS1005

Sterile ophthalmic devices (Cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits)
[Basic UDI-DI: 081131301MEDSURG01QY]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - WW/MD6/619286 - S2A 1.3 + TFR1.4
Authorized representative name and address (if relevant): Advena Ltd ; Tower Business Center 2nd Floor, Tower Street Swatar, BKR 4013 Malta
Previous certificate number: N/A
Change in between this certificate and previous one: N/A