

EC Certificate Production Quality Assurance System: Certificate US19/819943513

The management system of

MedOne Surgical, Inc.

670 Tallevast Road, Sarasota, FL, 34243, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits), knives and forceps for ophthalmic surgery.

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 December 2019 until 11 April 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 14 February 2003 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC/ 208342

Authorised by



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