EC Certificate Production Quality Assurance System: Certificate US03/58446

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: needles, cannulae, knives, brushes, tubing, picks, applicators, backflush devices, and ophthalmic instruments for ophthalmic surgery.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 April 2015 until 14 February 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 February 2018
Issue 6. Certified since 14 February 2003

Certification is based on reports numbered WW/ME 208342

Authorised by

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