MedOne®

April 7, 2024

Important Notice from MedOne Surgical, Inc.
Extension of MDD Directive 93/42/EEC

Re: **Extension of MDD Directive 93/42/EEC on Medical Devices, Annex V Certificate: US19/819943513,** Class IIa, Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits) for ophthalmic surgery.

To Whom It May Concern:

As you may be aware, the current MedOne EU Medical Device Directive Certificate expires on 11 April 2024. This letter is to serve as notification that MedOne's **MDD Certificate is hereby extended to 31 December 2028**, in accordance with the conditions of Article 120(3c) of the Medical Device Regulation MDR 2017/745.

Please be aware that Notified Bodies are not permitted to issue new MDD Certificates for MDD legacy devices under this same article. Legacy devices are those devices currently CE marked under prevailing MDD Certificates.

During the transitional period, between expiring MDD Certificates and the issuance of new MDR Certificates, the MDD CE certificate may be extended as long as the provisions in Article 120(3c) are fulfilled by the Manufacturer. MedOne has met all requirements and is providing the attached Manufacturer's Declaration, affirming compliance.

Additionally, MedOne notified body SGS – Belgium (1639), has provided the attached Confirmation Letter affirming receipt of formal application and execution of a written agreement, both in accordance with Annex VII of MDR. This letter endorses the continued compliance of MedOne devices to **31 December 2028**, as specified by the appropriate transition timeline presented in Article 120(3) of MDR (as amended by EU 2023/607).

As an MDR status update, MedOne has successfully passed two onsite MDR audits by our Notified Body, with no findings. The Technical Documentation audit is nearing completion, and represents the final step for approval of a MDR Certificate. Upon receipt, this MDR Certificate will be available immediately for distribution, as well as posted on the company website at www.MedOne.com.

We thank you for your understanding during this certificate transition, as well as your continued support of MedOne Products.

Sincerely,

Paul Butcher
RA/QA Manager

Attachment(s): MedOne Surgical, Inc. MDR Manufacturer's Declaration – CE Mark Extension
SGS – Belgium Confirmation Letter Reference: CLNB1639 - 208342

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