MedOne Surgical Inc.
670 Tallevast Road,
Sarasota,
FL 34243,
United States of America

08-April-2024

Confirmation Letter Reference: CLNB1639 - 208342

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MedOne Surgical Inc.
670 Tallevast Road,
Sarasota,
FL 34243,
United States of America
SRN Number: US-MF-000002763

EU Authorized Rep:
Advena Ltd.
Tower Business Centre 2nd Floor,
Tower Street Swatar,
BKR 4013
Malta
SRN Number: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the

NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Ian How
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Global Medical Device Certification Manager
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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Cannulae Family: Cannulas and accessories (cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits). Basic UDI: 081131301MEDSURG01QY	Class IIa	Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits)	N/A	Certificate #1; US19/819943513 NB: 1639

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:
"N/A: NB1639 is responsible for appropriate surveillance. "

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**

N/A: NB1639 is responsible for appropriate surveillance			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/21	Version 1	Initial issue
2024/04/08	Version 2	Updating the Basic UDI number