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# Declaration of Conformity

## MedOne Surgical, Inc. Sterile Cannula Family

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices.**

The undersigned declares and has sole responsibility that the products described in this document meet the Medical Device Regulation 2017/745 provisions that apply to them and the CE Mark may be affixed.

| | |
|---|---|
| **General Product Name:** | Sterile cannula family of medical devices - cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits) for ophthalmic use. |
| **Legal Manufacturer:** | MedOne Surgical, Inc.<br>670 Tallevast Road<br>Sarasota, Florida, USA 34243<br>SRN: US-MF-000002763 |
| **MedOne Surgical Basic UDI** | 081131301MEDSURG01QY |
| **Variants:** | As per Appendix II (this document) – Product Listing/Schedule |
| **Intended Use:** | Intended to infuse or aspirate fluids or gases during eye surgery. |
| **MDR Classification:** | Class IIa, Rule 6 for all devices covered in Scope:<br>Q021101 Ocular Irrigation and Aspiration Cannulas (all devices except for):<br>Q021113 Ophthalmic Surgery Instrument Kits, Single-Use (3275, 3315); Q021199 Ophthalmic Surgery Instruments, Single-Use (3228); Q0299 Ophthalmic Devices - Other (3223, 3243). |
| **EU Authorized Representative:** | Advena, Ltd.<br>Tower Business Centre<br>2nd Flr., Tower Street<br>Swatar, BKR 4013 Malta<br>SRN: MT-AR-000000234 |
| **Notified Body:** | SGS House Noordertaan<br>87 2030 Antwerp<br>Belgium<br>Notified Body ID 1639 |
| **MDR Conformity Assessment Route:** | MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III) |
| **EU MDR Certificate Number** | US25/00000348 |

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Name: Bruce Beckstein

Position: President, MedOne Surgical, Inc.

Signed: _____

Date: 18 November 2025

Place: Sarasota, Florida, USA

Who is the natural and legal person with responsibility for design, manufacture, packaging and labeling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

| Standard/Document Name | Description |
|---|---|
| 2017/745 | Regulation (EU) 201/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019+A11:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1:2021 | Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements |
| EN ISO 20417:2021 | Medical Devices – Information Supplied by the Manufacturers of Medical Devices |
| EN ISO 11137-1:2025 | Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization |
| EN ISO 11137-2:2015/A1:2023 | Sterilization of Health Care Products – Radiation Part 2 – Establishing the Sterilization Dose |
| EN ISO 80369-7:2021 | Small – bore Connectors for Liquids and Gases in Healthcare Applications |
| ISO 9626:2016 | Stainless Steel Tubing for the Manufacture of Medical Devices |
| EN ISO 14644-1:2015 | Cleanrooms and Associated Controlled Environments – Part 1 – Classification of Air Cleanliness by Particle Concentration |
| EN ISO 14644-2:2015 | Cleanrooms and Associated Controlled Environments – Part 2 – Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration |
| EN 17141:2020 | Cleanrooms and Associated Controlled Environments – Biocontamination Control |
| EN ISO 11607-1:2020A1:2023 | Packaging for Terminally Sterilized Medical Devices – Part 1 – Requirements for Materials, Sterile Barrier Systems and Packaging Systems |
| EN ISO 11607-2:2020+ A1:2023 | Packaging for Terminally Sterilized Medical Devices – Part 2 – Validation Requirements for Forming, Sealing and Assembly Processes |
| ASTM F1886-16(2024) | Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection |
| EN ISO 10993-1:2021 | Biological Evaluation of Medical Devices Part 1: Evaluation and Testing |
| EN ISO 10993-5:2009/A11:2025 | Biological Evaluation of Medical Devices Part 5: Tests for in vitro Cytotoxicity |
| EN ISO 10993-10:2023 | Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization |
| EN ISO 10993-11:2018 | Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity |

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## Appendix II – Product Listing/Schedule

| Catalogue Number | UDI-DI | Description/Name | EMDN Code |
|---|---|---|---|
| 3200 | 00811313012006 | Viscous Fluid Cannula 20g (4mm) | Q021101 |
| 3201 | 00811313012013 | Viscous Fluid Cannula 20g (6mm) | Q021101 |
| 3202 | 00811313012020 | Infusion Cannula 20g (4mm) | Q021101 |
| 3203 | 00811313012037 | Infusion Cannula 20g (6mm) | Q021101 |
| 3204 | 00811313012044 | MicroPick 25g | Q021101 |
| 3205 | 00811313012051 | Cannula XL 20g | Q021101 |
| 3206 | 00811313012068 | Cannula XL 23g | Q021101 |
| 3207 | 00811313012075 | Cannula XL 25g | Q021101 |
| 3208 | 00811313012082 | FlexTip™ Cannula XL 20g (3mm) | Q021101 |
| 3209 | 00811313012099 | FlexTip™ Cannula XL 23g (3mm) | Q021101 |
| 3210 | 00811313012105 | FlexTip™ Cannula XL 25g (3mm) | Q021101 |
| 3211 | 00811313012112 | FlexTip™ Cannula 20g (6mm) | Q021101 |
| 3214 | 00811313012143 | Cannula 20g | Q021101 |
| 3215 | 00811313012150 | FlexTip™ Brush 20g | Q021101 |
| 3218 | 00811313012181 | PolyTip® Cannula 25g/31g | Q021101 |
| 3219 | 00811313012198 | PolyTip® Cannula 25g/38g | Q021101 |
| 3220 | 00811313012204 | FlexTip™ Cannula 25g (3mm) | Q021101 |
| 3221 | 00811313012211 | FlexTip™ Cannula 25g (1mm) | Q021101 |
| 3222 | 00811313012228 | FlexTip™ Brush 25g | Q021101 |
| 3223 | 00811313012235 | Extension Tube [Hammer] | Q0299 |
| 3224 | 00811313012242 | FlexTip™ Cannula 25g (5mm) | Q021101 |
| 3225 | 00811313012259 | Cannula 25g | Q021101 |
| 3226 | 00811313012266 | VFI Cannula 25g | Q021101 |
| 3228 | 00811313012280 | Backflush Handle | Q021199 |
| 3229 | 00811313012297 | MicroPick 23g | Q021101 |
| 3230 | 00811313012303 | FlexTip™ Cannula 23g (1mm) | Q021101 |
| 3231 | 00811313012310 | FlexTip™ Cannula 23g (3mm) | Q021101 |
| 3232 | 00811313012327 | FlexTip™ Brush 23g | Q021101 |
| 3233 | 00811313012334 | PolyTip® Cannula 23g/38g | Q021101 |
| 3234 | 00811313012341 | Cannula 23g | Q021101 |
| 3235 | 00811313012358 | VFI Cannula 23g | Q021101 |
| 3237 | 00811313012372 | Dual Bore Cannula 20g | Q021101 |
| 3238 | 00811313012389 | FlexTip™ Cannula 20g (1mm) | Q021101 |
| 3239 | 00811313012396 | Dual Bore Cannula 23g | Q021101 |
| 3240 | 00811313012402 | Dual Bore Cannula 25g | Q021101 |
| 3241 | 00811313012419 | PolyTip® VFI Cannula 23g (10mm) | Q021101 |
| 3242 | 00811313012426 | FlexTip™ Cannula 23g (5mm) | Q021101 |
| 3243 | 00811313012433 | High Pressure Extension Tube | Q0299 |
| 3245 | 00811313012457 | VFI Infusion Cannula 25g | Q021101 |
| 3246 | 00811313012464 | VFI Infusion Cannula 23g | Q021101 |
| 3247 | 00811313012471 | Extendable PolyTip® Cannula 25g/38g | Q021101 |
| 3248 | 00811313012488 | Extendable PolyTip® Cannula 23g/38g | Q021101 |
| 3251 | 00811313012518 | FlexTip™ Cannula 25g (0.75mm) | Q021101 |
| 3252 | 00811313012525 | FlexTip™ Cannula 23g (0.75mm) | Q021101 |
| 3254 | 00811313012549 | PolyTip® Cannula 23g/38g (2mm) | Q021101 |
| 3255 | 00811313012556 | PolyTip® Cannula 25g/38g (2mm) | Q021101 |
| 3256 | 00811313012563 | PolyTip® Cannula 27g/38g (2mm) | Q021101 |
| 3257 | 00811313012570 | Cannula 27g | Q021101 |

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| Catalogue Number | UDI-DI | Description/Name | EMDN Code |
|---|---|---|---|
| 3258 | 00811313012587 | FlexTip™ Cannula 27g (1mm) | Q021101 |
| 3259 | 00811313012594 | PolyTip® Cannula 27g/38g | Q021101 |
| 3260 | 00811313012600 | FlexTip™ Cannula 27g (0.75mm) | Q021101 |
| 3261 | 10811313012614 | MicroTip Beveled Cannula 25g/40g | Q021101 |
| 3262 | 00811313012624 | PolyTip® Cannula 25g/33g (2mm) | Q021101 |
| 3263 | 10811313012638 | Nano Cannula 25g/48g | Q021101 |
| 3264 | 00811313012648 | FlexTip™ Brush 27g | Q021101 |
| 3273 | 00811313012730 | VFI Cannula 27g | Q021101 |
| 3274 | 10811313012744 | Visco Dissection Cannula 25g | Q021101 |
| 3275 | 00811313012754 | MicroDose™ Injection Kit | Q021113 |
| 3276 | 00811313012761 | Backflush Cannula 27g | Q021101 |
| 3278 | 00811313012785 | Backflush FlexTip™ 27g | Q021101 |
| 3286 | 00811313012860 | Backflush Cannula 23g | Q021101 |
| 3290 | 00811313012907 | Backflush FlexTip™ 23g | Q021101 |
| 3295 | 00811313012952 | Backflush Cannula 25g | Q021101 |
| 3296 | 00811313012969 | Backflush FlexTip™ 25g | Q021101 |
| 3298 | 00811313012983 | Extendable FlexTip™ Cannula 25g | Q021101 |
| 3299 | 00811313012990 | Extendable FlexTip™ Cannula 23g | Q021101 |
| 3300 | 00811313013003 | Oil Removal Cannula 23g [Kapran] | Q021101 |
| 3301 | 00811313013010 | VFI Infusion Cannula 27g | Q021101 |
| 3302 | 00811313013027 | Backflush SidePort 27g | Q021101 |
| 3305 | 00811313013058 | PolyVent™ Cannula 25g/38g | Q021101 |
| 3306 | 00811313013065 | PolyVent™ Cannula 23g/38g | Q021101 |
| 3307 | 00811313013072 | Extendable PolyVent™ Cannula 25g/38g | Q021101 |
| 3308 | 00811313013089 | Extendable PolyVent™ Cannula 23g/38g | Q021101 |
| 3311 | 00811313013119 | Olive Tip SC Cannula 23g [El Rayes] | Q021101 |
| 3315 | 00811313013157 | MicroDose™ SF Injection Kit | Q021113 |
| 3316 | 00811313013164 | GentleJect™ Cannula 25g | Q021101 |
| 3319 | 00811313013195 | PolyTip® Cannula 25g/38g Set | Q021101 |
| 3330 | 00811313013300 | AcuDepth™ Injector 30g x .7mm | Q021101 |
| 3331 | 00811313013317 | AcuDepth™ Injector 30g x 1mm | Q021101 |
| 3423 | 00811313014239 | DualBore SideFlō® Cannula 23g | Q021101 |
| 3425 | 00811313014253 | DualBore SideFlō® Cannula 25g | Q021101 |
| 3427 | 00811313014277 | DualBore SideFlō® Cannula 27g | Q021101 |
| 3507 | 00811313015076 | Extendable PolyTip® Cannula 25g/38g [Shiraga] | Q021101 |
| 3508 | 00811313015083 | Extendable FlexTip™ Brush 25g | Q021101 |

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**Version History:**

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 01 | E. Madsen | 24OCT2025 | New Document in accordance with MDR (EU) 2017/745 |
| 02 | E. Madsen | 13NOV2025 | Added MDR Conformity Assessment chapters, added place, added responsibilities, added EU regulation, added UDI-DI for each catalog number |