

**EU Medical Device Directive
93/42/EEC as Amended by 2007/47/EC
Declaration of Conformity**

Product(s): Endo Stratus™ Endoscopic Irrigation Pump and CO₂ Insufflator

Manufacturer: Medivators
Address: 14605 28th Avenue North
Minneapolis, MN 55447 USA

EU Representative: Cantel Medical Italy
Address: Cantel Medical (Italy) S.r.l.,
Via Laurentina, 169, 00040
Pomezia (RM), Italy

Model(s): **Endo Stratus Irrigation Pump – EGA-500, EGA-500E, EGA-500T**
Endo Stratus CO₂ Insufflator – EGA-501, EGA-501E, EGA-501T

Assessment of Product Based Upon:

Quality System Certification

ISO 13485 Certificate No: MD19.2990
Issued By: NSAI (0050)

CE Certification

CE Certificate No: 252.878
Conformity Assessment Route: Annex II
Issued By: NSAI (0050)

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Technical File

Prepared by: Regulatory Affairs

Product Classification:

Product classification based on the requirements of MDD Annex IX and EU Guidelines for Classification of Medical Devices MEDDEV 2.4.

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Class I
Class IIb

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Class IIa
Class III

Based on a review of the above documents, we hereby declare that the above product complies with the requirements of the EC Directive 93/42/EEC as amended by 2007/47/EC and the following standards:

ISO 14971

IEC 60601-1

IEC 60601-1-2

IEC-60601-2-18

Approvals:



Ashley Luloff
Regulatory Affairs Specialist
Medivators Inc.
9 November 2020

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