

Certificate

Certificate No.: MD 3321004-110

Manufacturer: **Hamilton Medical AG**

Via Crusch 8
7402 Bonaduz
Switzerland

D-U-N-S No.: 48-1492-312

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacturing, Distribution and Service of
Ventilators and Ventilator Systems

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 3321004-50

Issue Date: 2020-12-14

Effective Date: 2020-12-14

Expiry Date: 2023-07-08



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087651?locale=en
or calling 1-888-743-4652.

Certificate

Certificate No.: MD 3321004-110
Manufacturer: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland D-U-N-S No.: 48-1492-312	Design and Development, Distribution and Administration
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland D-U-N-S No.: 48-1492-312	Manufacturing and Service

Project No.: 3321004-50
Issue Date: 2020-12-14
Effective Date: 2020-12-14
Expiry Date: 2023-07-08



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087651?locale=en
or calling 1-888-743-4652.