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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1093044-1
Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
EUDAMED Single Registration No.:	CH-MF-000013790

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Date: 2025.04.30 11:08:35 EEST
Reason: MoldSign Signature
Location: Moldova
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Products:

Products of class IIa:
R9099 – Respiratory and Anaesthesia Devices – Others
R020101 – Breathing Circuits, Standard
R020102 – Breathing Circuits, Coaxial
R030102 – Air/Oxygen Masks and Nasal Cannulas

Products of class IIb:
R9099 – Respiratory and Anaesthesia Devices – Others
R060201 – Humidification Systems
Active Ventilation Humidification Systems

Products of class III:
Z120301 – Instruments to Support and Monitor Vital Signs
Anaesthesia and Pulmonary Ventilation Support Instruments

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	3321004-520
Effective date:	2024-01-12
Expiry date:	2025-12-23
Issue date:	2024-01-12

Sebastian Mniszek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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www.zlg.de
BS-MDR-091

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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1093044-1
Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
EUDAMED Single Registration No.:	CH-MF-000013790
Authorized representative(s):	medin Medical Innovations GmbH Adam-Geisler-Strasse 1 82140 Olching, Germany DE-AR-000006976

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-09-15
1	Scope extension, Products of class IIb, add. R9099	2023-03-15
2	Scope extension, Products of class III, add. Z120301	2023-06-21
3	Scope extension, Products of class IIb, add. R060201	2024-01-12

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