

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1093044-1
Certificate Holder: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland
Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1149905 040
Effective date: 2024-05-24
Expiry date: 2026-07-08
Issue date: 2024-05-24
Replaces certificate SX 1093044-1 issued 2024-04-23

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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development of ventilators and ventilator systems
/02	c/o Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing, distribution and servicing of ventilators and ventilator systems
/03	c/o Hamilton Medical UK Ltd. Unit J6, Fulford Drive Minworth Industrial Park, Minworth, SUTTON COLDFIELD B76 1DJ United Kingdom	Distribution and servicing of ventilators and ventilators systems
/05	c/o Hamilton Medical AG Parc Industrial Vial 12 7013 Domat/Ems Switzerland	Manufacture of ventilator sensors and tubing systems

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