

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19



Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

No.	Location
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland
/03	Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland

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