

Declaration of Conformity

We, Hamilton Medical AG,
Via Crusch 8, CH-7402
Bonaduz, Switzerland,
confirm that the following
products

Wir, Hamilton Medical AG,
Via Crusch 8, CH-7402
Bonaduz, Schweiz,
bestätigen, dass die
folgenden Produkte

La société Hamilton Medical
AG, Via Crusch 8, CH-7402
Bonaduz, Suisse, confirme
que les produits ci-dessous

CEDCL-HSENSOR, Attachment on page 2

meet the following EC
directive (including all
applicable amendments):

mit der folgenden EG-
Richtlinie (einschliesslich
aller zutreffenden
Änderungen) übereinstimmt:

sont en conformité avec le
directive CE suivant (y
compris leurs amendements,
le cas échéant):

EC Medical Device Directive:
93/42/EEC, Annex II, Art. 3

All listed products are
classified as class IIa.

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany

Registration No: HD 60137935 0001

Validity:

This declaration is valid for
products manufactured in
2020. Lot numbers are
traceable via
manufacturing protocols.
This declaration is valid in
connection with the final
inspection report.

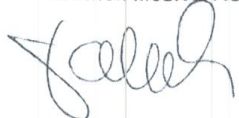
Gültigkeit:

Diese Konformitätserklärung
gilt für Produkte, welche 2020
produziert werden. Die
Losnummern sind über
Fertigungsnachweise
nachvollziehbar. Diese
Konformitätserklärung ist gültig
in Verbindung mit dem
Endprüfprotokoll.

Validité:

Cette déclaration est valable
pour les produits fabriqués en
2020. Les numéros de lot
peuvent être retracés par les
preuves de production. Cette
déclaration est valable
associée au rapport
d'inspection final.

Hamilton Medical AG



Jens Hallek
CEO

Bonaduz, 2019 -12- 16





TÜVRheinland®

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60137935 0001

Report No.: 21213508 015

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems
(see attachment for additional site included)
Replaces Approval, Registration No.: HD 60136804 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-07-09

Date: 2019-04-02

Notified Body

Dipl.-Ing. I. Munkler



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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





TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60137935 0001
Report No.: 21213508 015

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Date: 2019-07-09

Notified Body

I. Munkler
Dipl.-Ing. I. Munkler



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

Certificate Holder: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

including the locations according to annex

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-09 until 2021-01-08.

2020-06-12

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM 16031 01 00



TÜVRheinland
Precisely Right.



Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing of ventilators and ventilator systems

2020-06-12


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln