

Product catalog

This document reflects your selection of products from the Hamilton Medical online product catalog. The content is based on the following parameters:

Creation Date: **09 September 2022**
Country settings: **International**

Your selection: **Patient groups**
• Neonatal

Search keywords: **161079**

The online product catalog is subject to change without notice. The latest and most comprehensive product information is available online.

Legend

 Single use

 Reusable

 Autoclavable

 Adult

 Pediatric

 Neonatal



The packaging unit of each single product is marked within this box icon.

HAMILTON
MEDICAL

Software options

Product	Description
	161079   nCPAP option for HAMILTON-T1 Adds the ventilation modes nCPAP and nCPAP-PC. Requires neonatal option For ventilator: HAMILTON-T1 GTIN: 07630002804516



Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 (0)58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

Specifications are subject to change without notice. Some features are options. Not all features are available in all markets. INTELLiVENT-ASV is not available in the US. For all proprietary trademarks and third-party trademarks used by Hamilton Medical AG, see www.hamilton-medical.com/trademarks. © 2021 Hamilton Medical AG. All rights reserved.

Product catalog

This document reflects your selection of products from the Hamilton Medical online product catalog. The content is based on the following parameters:

Creation Date: **09 September 2022**

Country settings: **International**

Your selection: **Accessories & consumables**
● nCPAP

Patient groups
● Neonatal

Search keywords: **281975**

The online product catalog is subject to change without notice. The latest and most comprehensive product information is available online.

Legend

 Single use

 Reusable

 Autoclavable

 Adult

 Pediatric

 Neonatal



The packaging unit of each single product is marked within this box icon.

HAMILTON
MEDICAL

nCPAP

Product

Description



281975 nCPAP starter kit

1

2



Each kit contains:

20 measurement tapes

20 nCPAP generators with 20 pcs of foam wedge (2 x bag of 10)

10 masks of the size S, M and L, and 5 XL masks

10 nasal prongs of each size (micro, small, medium, medium wide, large, x-large, large wide)

10 bonnets of each size (xx-small, x-small, small, medium, large, x-large, xx-large, xxx-large)

Instruction for use

For ventilator: HAMILTON-C6/S1/G5/C3/C2/C1/C1 neo/T1/MR1

GTIN: 07630002800525



10064763 Fixation helper for HAMILTON nCPAP generator

10

2



Is part of [281975](#), [282330](#), [281976](#)

10pcs in a plastic bag

For ventilator: HAMILTON-C6/S1/G5/C3/C2/C1/C1 neo/T1/MR1

GTIN: 07630002812788

Materials: foam



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Product catalog

This document reflects your selection of products from the Hamilton Medical online product catalog. The content is based on the following parameters:

Creation Date: **10 September 2022**
Country settings: **International**

Your selection: **All categories**
Search keywords: **MSP369130**

The online product catalog is subject to change without notice. The latest and most comprehensive product information is available online.

Legend

 Single use

 Reusable

 Autoclavable

 Adult

 Pediatric

 Neonatal



The packaging unit of each single product is marked within this box icon.

HAMILTON
MEDICAL

Power supply

Product	Description
	1 MSP369130Li-Ion battery For ventilator: HAMILTON-C6 GTIN: 07630002809283



Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

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www.hamilton-medical.com

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Declaration of Conformity

We,

Wir,

Nous,

Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland,
(SRN: CH-MF-000013790)

confirm under our sole
responsibility that the
following products

bestätigen, unter unserer
alleinigen Verantwortung,
dass die folgenden Produkte

confirmons sous notre seule
responsabilité que les produits
suivants

CEDCL-HAM-C6, Attachment on page 2

comply with:

konform sind mit:

sont conformes aux:

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

All listed products are
classified as class IIb.

Alle aufgeführten Produkte sind
der Klasse IIb zugeordnet.

Tous les produits répertoriés
sont classés dans la classe IIb.



TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany
Registration No: HD 1093044-1



medin Medical Innovations GmbH
Adam-Geisler-Strasse 1
82140 Olching
Germany

Validity:

This declaration is valid for
products manufactured in
2022. 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 2022
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
2022. 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

06. DEZ. 2021

Bonaduz,

CEDCL-HAM-C6 Attachment

Product name	P/N	UDI-DI / GTIN	Basic UDI-DI / GMN
HAMILTON-C6	160021	07630002808590	76300028PN160021ZW

Declaration of Conformity

We,

Wir,

Nous,

Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland,
(SRN: CH-MF-000013790)

confirm under our sole
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following products

bestätigen, unter unserer
alleinigen Verantwortung,
dass die folgenden Produkte

confirmons sous notre seule
responsabilité que les produits
suivants

CEDCL-HAM-T1, Attachment on page 2

comply with:

konform sind mit:

sont conformes aux:

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

All listed products are
classified as class IIb.

Alle aufgeführten Produkte sind
der Klasse IIb zugeordnet.

Tous les produits répertoriés
sont classés dans la classe IIb.



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Tillystrasse 2
90431 Nürnberg
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Hamilton Medical AG

Jens Hallek
CEO

06. DEZ. 2021

Bonaduz,

CEDCL-HAM-T1 Attachment

Product name	P/N	UDI-DI / GTIN	Basic UDI-DI / GMN
HAMILTON-T1	161006	07630002801850	76300028PN1610062C
	1610060	07630002813532	76300028PN16100605C
	161009	07630002806091	76300028PN1610092J
	1610090	07630002813549	76300028PN16100905M

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.

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

The scope of certification includes the following manufacturing sites:

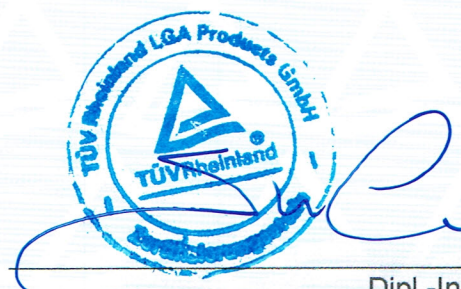
No.	Location
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland
/03	Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19



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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.

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1093044-1

Organization: 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.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19



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

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification also covers the following locations:

No.	Facility	Scope
/01	c/o Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems
/02	c/o Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing
/03	c/o Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing
/04	c/o Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland	Manufacturing of ventilator sensors and tubing systems

Report No.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19




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

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 2023-07-08.
First certification 2017

2022-05-18 (Change)



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/01	c/o Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	c/o Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	c/o 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
/04	c/o Hamilton Medical AG Industriepark Vial 4 7013 Domat/Ems Switzerland	Manufacture of ventilator sensors and tubing systems

2022-05-18 (Change)


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln