EU Declaration of Conformity

Manufacturer Name: Vapotherm Inc.

Manufacturer Address: 100 Domain Drive
Exeter, NH 03833
USA

SRN (Single Registration Number): US-MF-000006231

Authorized Representative Name: AJW Technology Consulting GmbH SRN (DE-AR-000004999)

Authorized Representative Address: Breite Straße 3
40213 Düsseldorf
Germany

Basic UDI-DI: 00841737102021

Name of the Device(s): HVT 2.0

Intended Purpose: The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult patients and pediatric patients (5 kg and up). The device is intended to be used in hospital, sub-acute facility and home-use settings.

HVT 2.0 provides high velocity nasal insufflation (HVNI) with simultaneous oxygen delivery to provide ventilatory support to spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. HVT 2.0 is not intended to provide total ventilatory requirements of the patient and not for use during field transport

Product code: R040201

Classification: Class IIa Rule 12

Common Specifications: None

Notified Body name: DQS Medizinprodukte GmbH

Notified Body Address: August-Schanz-Strasse 21
60433 Frankfurt am Main

Notified Body Identification number: 0297

Conformity assessment route: Vapotherm uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

EC conformity declaration according to Annex IX

This declaration of conformity is issued under the sole responsibility of Vapotherm. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DQS Medizinprodukte GbmH.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Lauren Worrell

……..……..

NAME: Lauren Worrell

TITLE: Sr. Regulatory Specialist

CE 0297

Place and date of issue:

Exeter, NH 03833, 21-Jan-2025

……..……..

Attachment to declaration of conformity for HVT 2.0

Catalogue number	Description	UDI -Each	UDI - Case
HVT20-UNIT	HVT 2.0 Unit	00841737103219	N/A
HVT20-NEL	HVT 2.0 Unit, Nellcor Compatible	00841737103950	N/A
HVT20-MAS	HVT 2.0 Unit, Masimo, Compatible	00841737103943	N/A
HVT-DPC	HVT 2.0 Disposable Patient Circuit	00841737103998	10841737103995 (Case of 5)
HVT-UKIT-GB	HVT 2.0 UKIT, Great Britain Version	00841737105466	N/A
HVT-UKIT-NISS	HVT 2.0 UKIT, NIST Version	00841737105473	N/A
HVT-UKIT-DISS-EU	HVT 2.0 UKIT, DISS EU Version	00841737105510	N/A
HVT-UKIT-DE	HVT 2.0 UKIT Germany	00841737105640	N/A
AAA-2	Aerosol Aerogen Adapter	00841737103936	10841737103933 (Case of 10)
HPF-TA-22	HVT 2.0/Precision Flow Trach Adapter, 22mm	00841737105565	10841737105562 (Case of 50)
HVT-ADPC	HVT 2.0 Aerosol Disposable Patient Circuit	00841737104001	10841737104008 (Case of 3)

REVISION LOG for DOC

Revision	Description of Change	Date
A	Initial Release	
B	Adding HVT-UKIT-DE	13-Jun-2023
C	Removing TA-22 and clarifying Product Code is the EMDN Code	21-Aug-2023
D	Adding HVT-ADPC	30-Oct-2023
E	Correction to Certificate Number Reference	30-Aug-2024
F	Removed Certificate ID Number	21-Jan-2025

Revision for Form 26-02-01	ECO#
A	20-010
B	22-034
B1	24-131