

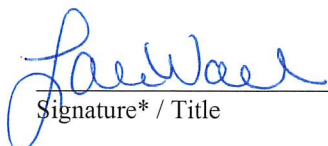
Declaration of Conformity

- I. **Manufacturer:** Vapotherm, Inc. 100 Domain Drive, Exeter NH 03833 USA
- II. **Authorized Representative:** AJW Technology Consulting GmbH,
Königsallee 206, 40215 Düsseldorf, Germany
- III. **Quality System:** Full quality assurance system in accordance with Annex II
– excluding Section 4 of Council Directive 93/42/EEC concerning medical
devices.
- IV. **Notified Body:** DQS Medizinprodukte GmbH - 0297, August-Schanz-Strasse
21, 60433 Frankfurt am Main
- V. **Classification:**
Class IIa per Rule 11 of Annex IX (Precision Flow Plus & Hi-VNI, HVT 2.0)
Class IIb per Rule 11 of Annex IX, MDD (OAM, HVT 2.0 with OAM)

VI. **Products(s):**

Precision Flow® (see Attachment I)
Precision Flow® Heliox (see Attachment II)
Precision Flow® Plus (see Attachment III)
Precision Flow® Hi-VNI (see Attachment IV)
Oxygen Assist Module® (See Attachment V)
HVT 2.0™ (See Attachment VI)

We, the manufacturer, hereby solely declare that the medical devices, listed above conform to the applicable provisions of EC Directive 93/42/EEC Annex II, concerning medical devices.

 sr. regulatory specialist
Signature* / Title

29-Mar-2022
Date

*Original signature on file

Expiration Date: 29-Mar-2023

CE 0297

NO. 291656 MR2

**VAPOTHERM®**

100 Domain Drive Exeter NH 03833 USA

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Revision Y

Date Issued 29-Mar-2022

Attachment I – Precision Flow® Unit**Master Precision Flow® Unit Part Number: 3000000**

Unit Serial Number of Effectivity: PF00001001-P

Unit Serial Number of Effectivity: PF00005021-S

Unit Serial Number of Effectivity: PF00010001-E

Unit Serial Number of Effectivity for RoHS Compliance: PF00020200-E

Product Reference	Catalog Number	Market Area
Precision Flow® Unit	PF-Unit	Base Unit for sale worldwide except for Brazil
Precision Flow® Unit	PF-UNIT-FLM-WAT	Precision Flow Classic Floor Model Units
Precision Flow® Unit	PF-UNIT-AT	Austria
Precision Flow® Unit	PF-UNIT-BE	Belgium
Precision Flow® Unit	PF-UNIT-EU	Czech Republic, Slovakia, Sweden
Precision Flow® Unit	PF-UNIT-FR	France
Precision Flow® Unit	PF-UNIT-DE	Germany
Precision Flow® Unit	PF-UNIT-IT	Italy
Precision Flow® Unit	PF-UNIT-NL	The Netherlands
Precision Flow® Unit	PF-UNIT-PL	Poland
Precision Flow® Unit	PF-UNIT-ES	Spain
Precision Flow® Unit	PF-UNIT-CH	Switzerland
Precision Flow® Unit	PF-UNIT-TR	Turkey
Precision Flow® Unit	PF-UNIT-GB	United Kingdom, Ireland

Country specific catalog numbers include language appropriate labeling and replacement parts for operating the device which may include; 3003011 Precision Flow O2 Sensor; 3000138 Precision Flow, DISS, O2 Filter Assembly; 3000139 Precision Flow, NIST, O2 Filter Assembly; 3000140 Precision Flow, DISS Air Filter Assembly; 3000141 Precision Flow, NIST Air Filter Assembly.



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Attachment II – Precision Flow® Heliox Unit

Master Precision Flow® Heliox Unit Part Number: 3200000

Unit Serial Number of Effectivity: PFH00801001-S

Unit Serial Number of Effectivity: PFH00800100-E

Unit Serial Number of Effectivity for RoHS Compliance: PFH00900000-E

Product Reference	Catalog Number	Market Area
Precision Flow® Heliox Unit	PFH-UNIT	Base Unit for catalog numbers listed below
Precision Flow® Heliox Unit	PFH-UNIT-FR	France
Precision Flow® Heliox Unit	PFH-UNIT-DE	Germany
Precision Flow® Heliox Unit	PFH-UNIT-IT	Italy
Precision Flow® Heliox Unit	PFH-UNIT-ES	Spain
Precision Flow® Heliox Unit	PFH-UNIT-GB	United Kingdom, Ireland
Precision Flow® Heliox Unit	PFH-UNIT-TR	Turkey

Country specific catalog numbers include language appropriate labeling and replacement parts for operating the device which may include; 3003011 Precision Flow O2 Sensor; 3000138 Precision Flow, DISS, O2 Filter Assembly; 3000139 Precision Flow, NIST, O2 Filter Assembly; 3000140 Precision Flow, DISS Air Filter Assembly; 3000141 Precision Flow, NIST Air Filter Assembly.

**Attachment III – Precision Flow® Plus Unit****Master Precision Flow® Plus Unit Part Number: PF-PLUS**

Unit Serial Number of Effectivity: PFP00000001-E

Product Reference	Catalog Number	Market Area
Precision Flow® Plus Unit	PF-PLUS	Base Unit for sale

Precision Flow® Plus Start Up Kit: PF-Plus-UKIT

Product Reference	Catalog Number	Market Area
PF Plus UKIT Great Britain	PF-Plus-UKIT-GB	Great Britain
PF Plus UKIT Germany	PF-Plus-UKIT-DE	Germany
PF Plus UKIT France	PF-Plus-UKIT-FR	France
PF Plus UKIT Turkey	PF-Plus-UKIT-TR	Turkey
PF Plus UKIT Slovakia	PF-Plus-UKIT-SK	Slovakia
PF Plus UKIT Denmark	PF-Plus-UKIT-DK	Denmark
PF Plus UKIT Spain	PF-Plus-UKIT-ES	Spain
PF Plus UKIT Poland	PF-Plus-UKIT-PL	Poland
PF Plus UKIT Italy	PF-Plus-UKIT-IT	Italy
PF Plus UKIT Czech Republic	PF-Plus-UKIT-CZ	Czech Republic
PF Plus UKIT Norway	PF-Plus-UKIT-NO	Norway

Country specific catalog numbers include language appropriate labeling and replacement parts for operating the device which may include; 3003011 Precision Flow O2 Sensor; 3000138 Precision Flow, DISS, O2 Filter Assembly; 3000139 Precision Flow, NIST, O2 Filter Assembly; 3000140 Precision Flow, DISS Air Filter Assembly; 3000141 Precision Flow, NIST Air Filter Assembly.



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Attachment IV – Precision Flow® Hi-VNI Unit

Master Precision Flow® Plus Unit Part Number: PF-PLUS

Unit Serial Number of Effectivity: PFPCXXXXXX-E

Product Reference	Catalog Number	Market Area
Precision Flow® Hi-VNI Unit	PF-PLUS	Base Unit for sale

Precision Flow® Hi-VNI Start Up Kit: PF-HVNI-UKIT

Product Reference	Catalog Number	Market Area
PF HiVNI UKIT Great Britain	HIVNI-UKIT-GB	Great Britain
PF HiVNI UKIT Germany	HIVNI-UKIT-DE	Germany
PF HiVNI UKIT France	HIVNI-UKIT-FR	France
PF HiVNI UKIT Turkey	HIVNI-UKIT-TR	Turkey
PF HiVNI UKIT Slovakia	HIVNI-UKIT-SK	Slovakia
PF HiVNI UKIT Denmark	HIVNI-UKIT-DK	Denmark
PF HiVNI UKIT Spain	HIVNI-UKIT-ES	Spain
PF HiVNI UKIT Poland	HIVNI--UKIT-PL	Poland, Bulgaria, Romania
PF HiVNI UKIT Italy	HIVNI-UKIT-IT	Italy
PF HiVNI UKIT Czech Republic	HIVNI-UKIT-CZ	Czech Republic
PF HiVNI UKIT Norway	HIVNI-UKIT-NO	Norway
PF HiVNI UKIT Portugal	HIVNI-UKIT-PT	Portugal

Country specific catalog numbers include language appropriate labeling and replacement parts for operating the device which may include; 3003011 Precision Flow O2 Sensor; 3000138 Precision Flow, DISS, O2 Filter Assembly; 3000139 Precision Flow, NIST, O2 Filter Assembly; 3000140 Precision Flow, DISS Air Filter Assembly; 3000141 Precision Flow, NIST Air Filter Assembly.



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Attachment V – Oxygen Assist Module (OAM)

OAM Unit Part Number: PF-OAM

Unit Serial Number of Effectivity: 1921300001

<u>Product Reference</u>	<u>Catalog Number</u>	<u>Market Area</u>
Oxygen Assist Module (OAM)	PF-OAM	Base Unit for sale worldwide

OAM Start Up Kit

<u>Product Reference</u>	<u>Catalog Number</u>	<u>Market Area</u>
OAM UKIT Great Britain	PF-OAM-UKIT-GB	United Kingdom, Ireland
OAM UKIT Germany	PF-OAM-UKIT-DE	Germany
OAM UKIT Italy	PF-OAM-UKIT-IT	Italy



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Attachment VI – HVT 2.0™

HVT 2.0™ Unit Part Number:

Unit Serial Number of Effectivity: HVT001000

<u>Product Reference</u>	<u>Catalog Number</u>	<u>Market Area</u>
HVT 2.0 Unit (Unpopulated, Masimo I/O Board)	HVT 2.0-UNIT	Base Unit for sales worldwide
HVT 2.0 Unit (Unpopulated, Nellcor I/O Board)	HVT 2.0N-UNIT	Base Unit for sales worldwide
HVT 2.0 Unit (Populated, Masimo)	HVT 2.0MAS-UNIT	Base Unit for sales worldwide
HVT 2.0 Unit (Populated, Nellcor)	HVT 2.0NEL-UNIT	Base Unit for sales worldwide

**VAPOTHERM®**

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REVISION LOG for DOC

<u>Rev</u>	<u>Description</u>	<u>Date</u>
A	Original Release	November 14, 2016
B	Update market area	March 22, 2017
C	Update Section 2 Language	April 6, 2017
D	Addition of UKIT(s) France, Germany, Great Britain	July 21, 2017
E	Updated address to 100 Domain Drive	August 1, 2017
F	Updated expiration date	August 21, 2017
G	Addition of Turkey UKIT	September 11, 2017
H	Addition of Slovakia and Denmark UKITS	September 28, 2017
J	Addition of Spain, Poland, Italy and Czech Republic UKITS	January 8, 2018
K	Minor format updates, addition of reusable startup Kit components.	August 16, 2018
L	Added Attachment II to include HiVNI SKUs and UKITs	February 19, 2019
M	Update Expiration Date	August 13, 2019
N	Updated to include entire PF Family Product SKUs	August 27, 2019
P	Addition of Norway UKIT	November 4, 2019
R	Updating EC Rep Address	February 27, 2020
T	Addition of Norway and Portugal HiVNI UKIT	April 9, 2020
U	Updating OAM information	May 19, 2020
V	Addition of HVT 2.0 Information	October 26, 2020
W	Revising Expiration Date	August 30, 2021
X	Adding PF-UNIT-FLM-WAT	November 15, 2021
Y	Adding Bulgaria and Romania to HiVNI--UKIT-PL market area	March 29, 2022