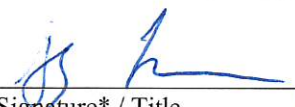


Declaration of Conformity

- 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:**
Precision Flow and Accessories Class IIa per Rule 2 of Annex IX
Oxygen Assist Module Class IIb per Rule 11 of Annex IX
- VI. **Product(s):**

Precision Flow® Accessory Products - (see Attachment I)

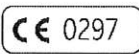
We, the manufacturer, hereby solely declare that the medical devices, listed above conform to the applicable provisions of EC Directive 93/42/EEC Annex II, concerning medical devices.

 Regulatory Manager
Signature* / Title

30-Jan-2020
Date

*Original signature on file

Expiration Date: January 30, 2021



NO. 291656 MR2

Attachment I- Precision Flow® Accessory Products

DISPOSABLE ACCESSORIES:

PF-DPC-HIGH	Precision Flow Disposable Patient Circuit – High Flow
PF-DPC-LOW	Precision Flow Disposable Patient Circuit – Low Flow
PF-NODPC-HIGH	PF-NO DWP High Kit
PF-NODPC-LOW	PF-NO DWP Low Kit
PF-DPC-HIGH-WBA	Disposable Patient Circuit – WBA Bundle High Flow
PF-DPC-LOW-WBA	Disposable Patient Circuit – WBA Bundle Low Flow
PF-OAMDPC-Low	Disposable Patient Circuit – Oxygen Assist Module – Low Flow
MA1700	Nasal Cannula (Adult)
MN1100A	Nasal Cannula (Premature)
MN1100B	Nasal Cannula (Neonatal)
MI1300	Nasal Cannula (Infant)
MI1300B	Nasal Cannula (Intermediate Infant)
MP1500	Nasal Cannula (Pediatric / Adult Small)
MPS1500	Nasal Cannula (Pediatric – Small)
SOLO1300	Infant Nasal Cannula
TA-22	Tubing Adapter
AAA-1	Aerogen Assembly (Aeroneb Aerosol Adapter)
PF-WBA	Precision Flow Water Bottle Adapter

ADDITIONAL ACCESSORIES:

PF-Stand	Precision Flow, Stand (IV Pole for Precision Flow Unit)
PF-VTU-NIST	Precision Flow, VapoTherm Transfer Unit – NIST
PF-VTU-DISS	Precision Flow, VapoTherm Transfer Unit – DISS
PF-OAM	Precision Flow, Oxygen Assist Module

REVISION LOG for DOC

<u>Rev</u>	<u>Description</u>	<u>Date</u>
New	Original Release	8/31/09
A	Update for Current CE Requirements	3/21/10
B	Update for Accessory Listing	6/18/10
C	Update Declaration of Conformity for Accessory Listing	12/12/10
D	Update Declaration of Conformity for Accessory List Items	1/28/11
E	Update Declaration of Conformity for Accessory List Items	12/1/11
F	Update Declaration of Conformity for PFH UKIT Accessory List Items	4/19/12
G	Removed Expiration Date/Update List Items	5/30/13
H	Update of Address	8/30/13
I	Update Expiration Date, DQS Address	11/26/13
J	Update Address on pages 2 and 3	12/10/13
K	Revise Classification Rule from 2 to 11	12/27/13
L	Add Heliox DPC and Heliox Evaluation DPC	4/30/14
M	Add Single PF DPC High and Low	6/5/14
N	Add Startup Kits for Netherlands and Poland and Water Bottle Adapter	8/8/14
O	Update Startup Kits to reflect current offerings; Update Authorized Rep Address	4/2/15
P	Update Expiration Date	4/29/15
Q	Update PF-UKIT Catalog Numbers and Descriptions	5/11/15
R	Remove Evaluation DPCs	7/23/15
S	Add PF-UKIT-BR for Brazil	8/17/15
T	Add PF-UKIT-MX for Mexico	2/22/16
U	Remove all non-European catalog numbers from list per instruction from DQS Auditor	3/2/16
V	Revise PFH-UKIT SKUs to reflect current SKUs	3/29/16
W	Add Breathlite Arm Band	6/6/2016
X	Add PFH-UKIT-TR for Turkey	1/3/2017
Y	Change address from 22 Industrial Drive to 100 Domain Drive	01/16/17
Z	Add PF-VTU-NIST	08/01/17
AA	Add PF-VTU-DISS	1/30/18
AB	Addition of DPC-WBA SKUs, removal of PFH-DPC SKUs, removal of Insolare Cannulas and transfer of replaceable UKIT components to the Precision Flow Declaration of Conformity	08/16/18
AC	Removed PFR-DPC-HIGH, PFR-DPC-LOW, PF-VTC-HIGH & PF-VTC-LOW, removed description of DPC components	02/13/19
AD	Update Expiration Date	08/13/19
AE	Addition of Oxygen Assist Module	1/30/2020