

**Declaration of Conformity – Ventoux Ventilator**

We, Flight Medical Innovations Ltd. hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the EC Conformity Certificate, reference number D1068300023: (Report P18-00805-122824), issued on 20.02.2020 and delivered by MDC Medical Device Certification GmbH, located at Kriegerstrabe 6, Stuttgart D-70191 Germany, Notified Body Identification Number 0483, and conform to the required Council Directive 93/42/EEC amended by Directive 2007/47/EC of 5 September 2007, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within the following categories:

- The Ventilator, Cuff Control and Flow Sensors are classified as class IIb, according to rule 09 per Annex IX of MDD 93/42/EEC amended by MDD 47/2007/EC .
- The SpO2 Monitoring Module,
Capnography Monitoring Module are classified as Class IIa, according to Rule 10 of Annex IX of the Directive, and meet the provisions of the EC-Directive which apply to them:
- Exhalation Valves, Pneumatic Connectors, Filters and Patient Circuits are classified as class IIa, according to rule 02 per Annex IX of MDD 93/42/EEC amended by MDD 47/2007/EC.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex II section 3 of the EC-Directive. The conformity of the production quality assurance set out in Annex II section 3, is described in the said CE Marking of Conformity Certificate, issued and delivered MDC Medical Device Certification GmbH.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2016, Quality System Certificate with reference number D1068300022.

This Declaration of Conformity covers products as specified in the product list Annex, belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:



Flight Medical

DECLARATION OF CONFORMITY

Manufacturer:

Flight Medical Innovations

7 Hatnufa St.

Petach Tikva 4951025

Israel

Authorized European Representative

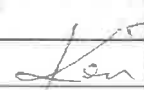
Obelis S.A.

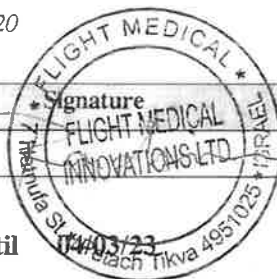
Av. De Tervueren 34, Bte- 44, B-1040 Bruxelles

BELGIUM

Place and Date of Issue

Petach Tikva, Israel, 17.03.2020

Name of Authorized Person	Signature
Ken Raichman QA/RA Manager	



This Declaration of Conformity is Valid until

Product List

The product list belongs to the Declaration of Conformity identified by DOC-0426-A05 and specifies the CE marked products concerned that Flight Medical Innovations Ltd. intends to distribute in conformity with the provisions of the Council Directive 2007/47/EC concerning medical devices. The following list identifies the products by name (or description and by part number.

**DECLARATION OF CONFORMITY****Ventoux Configurations****1** Cap – Capnography **2** Orid-Oridion **3** Ph-Phillips**4** Nellcor SpO2 – oximetry**5** CUFF – cuff control **6** Mix – Internal O2 Mixer

#	P/N	Configuration
1	VX-08-0-000	VX-8
2	VX-08-0-M00	VX-8 Cap ¹ :Orid ²
3	VX-08-0-P00	VX-8 Cap:Ph ³
4	VX-08-0-0N0	VX-8 Nellcor SPO2 ⁴
5	VX-08-0-MN0	VX-8 Cap:Orid Nellcor SPO2
6	VX-08-0-PN0	VX-8 Cap:Ph Nellcor SPO2
7	VX-08-0-001	VX-8 CUFF ⁵
8	VX-08-0-M01	VX-8 Cap:Orid CUFF
9	VX-08-0-P01	VX-8 Cap:Ph CUFF
10	VX-08-0-0N1	VX-8 Nellcor SPO2 CUFF
11	VX-08-0-MN1	VX-8 Cap:Orid Nellcor SPO2 CUFF
12	VX-08-0-PN1	VX-8 Cap:Ph Nellcor SPO2 CUFF
13	VX-08-1-000	VX-8 O2 Mix ⁶
14	VX-08-1-M00	VX-8 O2 Mix Cap:Orid
15	VX-08-1-P00	VX-8 O2 Mix Cap:Ph
16	VX-08-1-0N0	VX-8 O2 Mix Nellcor SPO2
17	VX-08-1-MN0	VX-8 O2 Mix Cap:Orid Nellcor SPO2
18	VX-08-1-PN0	VX-8 O2 Mix Cap:Ph Nellcor SPO2
19	VX-08-1-001	VX-8 O2 Mix CUFF
20	VX-08-1-M01	VX-8 O2 Mix Cap:Orid CUFF
21	VX-08-1-P01	VX-8 O2 Mix Cap:Ph CUFF
22	VX-08-1-0N1	VX-8 O2 Mix Nellcor SPO2 CUFF
23	VX-08-1-MN1	VX-8 O2 Mix Cap:Orid Nellcor SPO2 CUFF
24	VX-08-1-PN1	VX-8 O2 Mix Cap:Ph Nellcor SPO2 CUFF
25	VX-12-0-000	VX-12



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26	VX-12-0-M00	VX-12 Cap:Orid
27	VX-12-0-P00	VX-12 Cap:Ph
28	VX-12-0-0N0	VX-12 Nellcor SPO2
29	VX-12-0-MN0	VX-12 Cap:Orid Nellcor SPO2
30	VX-12-0-PN0	VX-12 Cap:Ph Nellcor SPO2
31	VX-12-0-001	VX-12 CUFF
32	VX-12-0-M01	VX-12 Cap:Orid CUFF
33	VX-12-0-P01	VX-12 Cap:Ph CUFF
34	VX-12-0-0N1	VX-12 Nellcor SPO2 CUFF
35	VX-12-0-MN1	VX-12 Cap:Orid Nellcor SPO2 CUFF
36	VX-12-0-PN1	VX-12 Cap:Ph Nellcor SPO2 CUFF
37	VX-12-1-000	VX-12 O2 Mix
38	VX-12-1-M00	VX-12 O2 Mix Cap:Orid
39	VX-12-1-P00	VX-12 O2 Mix Cap:Ph
40	VX-12-1-0N0	VX-12 O2 Mix Nellcor SPO2
41	VX-12-1-MN0	VX-12 O2 Mix Cap:Orid Nellcor SPO2
42	VX-12-1-PN0	VX-12 O2 Mix Cap:Ph Nellcor SPO2
43	VX-12-1-001	VX-12 O2 Mix CUFF
44	VX-12-1-M01	VX-12 O2 Mix Cap:Orid CUFF
45	VX-12-1-P01	VX-12 O2 Mix Cap:Ph CUFF
46	VX-12-1-0N1	VX-12 O2 Mix Nellcor SPO2 CUFF
47	VX-12-1-MN1	VX-12 O2 Mix Cap:Orid Nellcor SPO2 CUFF
48	VX-12-1-PN1	VX-12 O2 Mix Cap:Ph Nellcor SPO2 CUFF

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Ventoux Patient Circuits

#	P/N	Description	Note
1	VX64-0001	VX-DL Single Use Universal P.C.	Adult DL
2	VX64-0002	VX-DL Single Use P.C.	
3	VX64-0003	VX- DL Autoclavable P.C.	
4	VX64-0004	VX- DL Autoclavable F.S. Kit	
5	VX64-0005	VX- DL F.S. Kit	
6	VX64-0006	VX- DL Ped. Single Use P.C.	Pediatric DL
7	VX64-0007	VX- DL Ped. Autoclavable F.S. Kit	
8	VX64-0008	VX- DL Ped. F.S. Kit	
9	VX64-0009	VX- SL Single Use P.C.	Adult SL
10	VX64-0010	VX- SL Autoclavable P.C.	
11	VX64-0011	VX- SL F.S. Kit	
12	VX64-0012	VX- SL Autoclavable F.S. Kit	
13	VX64-0013	VX- SL Single Use Ped. P.C.	Pediatric SL
14	VX64-0014	VX- SL Ped. F.S. Kit	
15	VX64-0015	VX- SL Ped. Autoclavable F.S. Kit	
16	VX64-0016	VX-DL Ped. Single Use P.C. w/RD	Pediatric DL w/ RD
17	VX64-0017	VX-DL Ped. Autoclavable F.S. Kit w/RD	
18	VX64-0018	VX-DL Ped. F.S. Kit w/RD	
19	VX64-0019	VX- SL Single Use Ped. P.C. w/ RDS VX-SL Single Use Ped. P.C. w/RD	Pediatric SL w/ RD
20	VX64-0020	VX-SL Ped. F.S. Kit w/RD	
21	VX64-0021	VX-SL Ped. Autoclavable F.S. Kit w/RD	

Place and Date of Issue

Petach Tikva, Israel, 20/02/20

Name of Authorized Person

Ken Raichman, Director of QA & Regulatory Affairs

Signature



Addendum to Declaration of Conformity (DoC)

This addendum refers to the Declaration of Conformity DOC-0426 Rev. A05, issued on March 17, 2020 Issued under Directive 93/42/EEC (MDD)

The purpose of this addendum is:

1. To include Device basic UDI-DI:

The list in the DoC identifies the products by name (or description), by part number and by the Basic UDI-DI number: **7290017856VX812TC2**

2. Extend the validity of the DoC based on the notified body conformation letter.

We hereby declare, in accordance to the confirmation letter received on May 27, 2023 from MDC, (Flight Medical's appropriate EU Notified Body), that the motioned products in the DoC meet the current transitional provisions according to Article 120 of the Medical Device Regulation **MDR** (2017/745), and as amended by Regulation (EU) 2023/607, and as a consequence, the existing EC Certificate of Conformity for Ventoux (reference number D1068300025) is valid until 2028-12-31.

3. Update the product list with further specifications of items already included in the product list of the original DoC.

#	Description	Part Number
1	VX-8" Packed	VX-08-0-000-PK
2	VX-8" Cap:Orid Packed	VX-08-0-M00-PK
3	VX-8" Cap:Ph Packed	VX-08-0-P00-PK
4	VX-8" Nellcor SPO2 Packed	VX-08-0-0N0-PK
5	VX-8" Cap:Orid Nellcor SPO2 Packed	VX-08-0-MN0-PK
6	VX-8" Cap:Ph Nellcor SPO2 Packed	VX-08-0-PN0-PK
7	VX-8" Cuff Packed	VX-08-0-001-PK
8	VX-8" Cap:Orid Cuff Packed	VX-08-0-M01-PK
9	VX-8" Cap:Ph Cuff Packed	VX-08-0-P01-PK
10	VX-8" Nellcor SPO2 Cuff Packed	VX-08-0-0N1-PK
11	VX-8" Cap:Orid Nellcor SPO2 Cuff Packed	VX-08-0-MN1-PK

12	VX-8" Cap:Ph Nellcor SPO2 Cuff Packed	VX-08-0-PN1-PK
13	VX-8" O2 Mix Packed	VX-08-1-000-PK
14	VX-8" O2 Mix Cap:Orid Packed	VX-08-1-M00-PK
15	VX-8" O2 Mix Cap:Ph Packed	VX-08-1-P00-PK
16	VX-8" O2 Mix Nellcor SPO2 Packed	VX-08-1-0N0-PK
17	VX-8" O2 Mix Cap:Orid Nellcor SPO2 Packed	VX-08-1-MN0-PK
18	VX-8" O2 Mix Cap:Ph Nellcor SPO2 Packed	VX-08-1-PN0-PK
19	VX-8" O2 Mix Cuff Packed	VX-08-1-001-PK
20	VX-8" O2 Mix Cap:Orid Cuff Packed	VX-08-1-M01-PK
21	VX-8" O2 Mix Cap:Ph Cuff Packed	VX-08-1-P01-PK
22	VX-8" O2 Mix Nellcor SPO2 Cuff Packed	VX-08-1-0N1-PK
23	VX-8" O2 Mix Cap:Orid Nellcor SPO2 Cuff Packed	VX-08-1-MN1-PK
24	VX-8" O2 Mix Cap:Ph Nellcor SPO2 Cuff Packed	VX-08-1-PN1-PK

#	Configuration	Packed
25	VX-12" Packed	VX-12-0-000-PK
26	VX-12" Cap:Orid Packed	VX-12-0-M00-PK
27	VX-12" Cap:Ph Packed	VX-12-0-P00-PK
28	VX-12" Nellcor SPO2 Packed	VX-12-0-0N0-PK
29	VX-12" Cap:Orid Nellcor SPO2 Packed	VX-12-0-MN0-PK
30	VX-12" Cap:Ph Nellcor SPO2 Packed	VX-12-0-PN0-PK
31	VX-12" Cuff Packed	VX-12-0-001-PK
32	VX-12" Cap:Orid Cuff Packed	VX-12-0-M01-PK
33	VX-12" Cap:Ph Cuff Packed	VX-12-0-P01-PK
34	VX-12" Nellcor SPO2 Cuff Packed	VX-12-0-0N1-PK
35	VX-12" Cap:Orid Nellcor SPO2 Cuff Packed	VX-12-0-MN1-PK
36	VX-12" Cap:Ph Nellcor SPO2 Cuff Packed	VX-12-0-PN1-PK

37	VX-12" O2 Mix Packed	VX-12-1-000-PK
38	VX-12" O2 Mix Cap:Orid Packed	VX-12-1-M00-PK
39	VX-12" O2 Mix Cap:Ph Packed	VX-12-1-P00-PK
40	VX-12" O2 Mix Nellcor SPO2 Packed	VX-12-1-0N0-PK
41	VX-12" O2 Mix Cap:Orid Nellcor SPO2 Packed	VX-12-1-MN0-PK
42	VX-12" O2 Mix Cap:Ph Nellcor SPO2 Packed	VX-12-1-PN0-PK
43	VX-12" O2 Mix Cuff Packed	VX-12-1-001-PK
44	VX-12" O2 Mix Cap:Orid Cuff Packed	VX-12-1-M01-PK
45	VX-12" O2 Mix Cap:Ph Cuff Packed	VX-12-1-P01- PK
46	VX-12" O2 Mix Nellcor SPO2 Cuff Packed	VX-12-1-0N1-PK
47	VX-12 O2 Mix Cap:Orid Nellcor SPO2 Cuff Packed	VX-12-1-MN1-PK
48	VX-12 O2 Mix Cap:Ph Nellcor SPO2 Cuff Packed	VX-12-1-PN1-PK

Patient Circuits :

#	P/N	Description	Note
1	VX64-0001	VX- DL Adult Single Use P.C. Universal	Adult DL
2	VX64-0002	VX-DL Adult Single Use P.C.	
3	VX64-0003	VX-DL Adult Autoclavable P.C.	
4	VX64-0004	VX-DL Adult Autoclavable F.S. Kit	
5	VX64-0005	VX-DL Adult Single Use F.S. Kit	
6	VX64-0006	VX-DL Ped. Single Use P.C.	Pediatric DL
7	VX64-0007	VX-DL Ped. Autoclavable F.S. Kit	
8	VX64-0008	VX-DL Ped. Single Use F.S. Kit	
9	VX64-0009	VX-SL Adult Single Use P.C	Adult SL
10	VX64-0010	VX-SL Adult Autoclavable P.C.	
11	VX64-0011	VX-SL Adult Single Use F.S. Kit	
12	VX64-0012	VX-SL Adult Autoclavable F.S. Kit	
13	VX64-0013	VX-SL Ped. Single Use P.C.	Pediatric SL
14	VX64-0014	VX-SL Ped. Single Use F.S. Kit	

15	VX64-0015	VX-SL Ped. Autoclavable F.S. Kit	
16	VX64-0016	VX-DL Ped. Single Use P.C. w/RD	
17	VX64-0017	VX-DL Ped. Autoclavable F.S. Kit w/RD	Pediatric DL w/ RD
18	VX64-0018	VX-DL Ped. Single Use F.S. Kit w/RD	
19	VX64-0019	VX-SL Ped. Single Use P.C. w/RD	
20	VX64-0020	VX-SL Ped. Single Use F.S. Kit w/RD	Pediatric SL w/ RD
21	VX64-0021	VX-SL Ped. Autoclavable F.S. Kit w/RD	

Additional Items:

	Part Number	Description
1	FLM-0030	Cuff Extender
2	SUB-0148	F60 Internal Oxygen Supply Hose
3	Kit 0121	Pneumatic Connectors

Place and Date of Issue

Petach Tikva, Israel, 24.05.25

Signature



This extend the validity of the declaration of conformity until 31.12.28