

## **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 D1068300025: (Report P20-00118-167895), issued on 11.08.2020 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 D1068300025.

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: \_\_\_\_\_

**Manufacturer:**

*Flight Medical Innovations  
7 Hatnufa St.  
Petach Tikva 4951025  
Israel*

**Authorized European Representative**

*Obelis S.A.  
Boulevard Général Wahis 53, 1030 Brussels  
BELGIUM*

*Place and Date of Issue*

*Petach Tikva, Israel, 09/05/2023*

<b>Name of Authorized Person</b>	<b>Signature</b>
<b>Ken Raichman QA/RA Manager</b>	<b>signed</b>

**This Declaration of Conformity is Valid until 26/05/2024**

**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), by part number AND BY Basic UDI-DI number **7290017856VX812TC2**.

Device's part number and description

#	Description	Part Number
1	VX-8" Final Assy	VX-08-0-000
2	VX-8" Cap:Orid Final Assy	VX-08-0-M00
3	VX-8" Cap:Ph Final Assy	VX-08-0-P00
4	VX-8" Nellcor SPO2 Final Assy	VX-08-0-0N0
5	VX-8" Cap:Orid Nellcor SPO2 Final Assy	VX-08-0-MN0
6	VX-8" Cap:Ph Nellcor SPO2 Final Assy	VX-08-0-PN0
7	VX-8" Cuff Final Assy	VX-08-0-001
8	VX-8" Cap:Orid Cuff Final Assy	VX-08-0-M01
9	VX-8" Cap:Ph Cuff Final Assy	VX-08-0-P01
10	VX-8" Nellcor SPO2 Cuff Final Assy	VX-08-0-0N1
11	VX-8" Cap:Orid Nellcor SPO2 Cuff Final Assy	VX-08-0-MN1
12	VX-8" Cap:Ph Nellcor SPO2 Cuff Final Assy	VX-08-0-PN1
13	VX-8" O2 Mix Final Assy	VX-08-1-000
14	VX-8" O2 Mix Cap:Orid Final Assy	VX-08-1-M00
15	VX-8" O2 Mix Cap:Ph Final Assy	VX-08-1-P00
16	VX-8" O2 Mix Nellcor SPO2 Final Assy	VX-08-1-0N0
17	VX-8" O2 Mix Cap:Orid Nellcor SPO2 Final Assy	VX-08-1-MN0
18	VX-8" O2 Mix Cap:Ph Nellcor SPO2 Final Assy	VX-08-1-PN0
19	VX-8" O2 Mix Cuff Final Assy	VX-08-1-001
20	VX-8" O2 Mix Cap:Orid Cuff Final Assy	VX-08-1-M01
21	VX-8" O2 Mix Cap:Ph Cuff Final Assy	VX-08-1-P01
22	VX-8" O2 Mix Nellcor SPO2 Cuff Final Assy	VX-08-1-0N1
23	VX-8" O2 Mix Cap:Orid Nellcor SPO2 Cuff Final Assy	VX-08-1-MN1
24	VX-8" O2 Mix Cap:Ph Nellcor SPO2 Cuff Final Assy	VX-08-1-PN1



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

## Appendix A

Device's package part number and description

#	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
33	VX-12" Packed	VX-12-0-000-PK
34	VX-12" Cap:Orid Packed	VX-12-0-M00-PK
35	VX-12" Cap:Ph Packed	VX-12-0-P00-PK
37	VX-12" Nellcor SPO2 Packed	VX-12-0-0N0-PK
38	VX-12" Cap:Orid Nellcor SPO2 Packed	VX-12-0-MN0-PK
39	VX-12" Cap:Ph Nellcor SPO2 Packed	VX-12-0-PN0-PK
41	VX-12" Cuff Packed	VX-12-0-001-PK
42	VX-12" Cap:Orid Cuff Packed	VX-12-0-M01-PK
43	VX-12" Cap:Ph Cuff Packed	VX-12-0-P01-PK
45	VX-12" Nellcor SPO2 Cuff Packed	VX-12-0-0N1-PK
46	VX-12" Cap:Orid Nellcor SPO2 Cuff Packed	VX-12-0-MN1-PK
47	VX-12" Cap:Ph Nellcor SPO2 Cuff Packed	VX-12-0-PN1-PK
49	VX-12" O2 Mix Packed	VX-12-1-000-PK
50	VX-12" O2 Mix Cap:Orid Packed	VX-12-1-M00-PK
51	VX-12" O2 Mix Cap:Ph Packed	VX-12-1-P00-PK
53	VX-12" O2 Mix Nellcor SPO2 Packed	VX-12-1-0N0-PK
54	VX-12" O2 Mix Cap:Orid Nellcor SPO2 Packed	VX-12-1-MN0-PK
55	VX-12" O2 Mix Cap:Ph Nellcor SPO2 Packed	VX-12-1-PN0-PK
57	VX-12" O2 Mix Cuff Packed	VX-12-1-001-PK
58	VX-12" O2 Mix Cap:Orid Cuff Packed	VX-12-1-M01-PK
59	VX-12" O2 Mix Cap:Ph Cuff Packed	VX-12-1-P01- PK
61	VX-12" O2 Mix Nellcor SPO2 Cuff Packed	VX-12-1-0N1-PK
62	VX-12 O2 Mix Cap:Orid Nellcor SPO2 Cuff Packed	VX-12-1-MN1-PK
63	VX-12 O2 Mix Cap:Ph Nellcor SPO2 Cuff Packed	VX-12-1-PN1-PK

**Ventoux Patient Circuits**

#	P/N	Description	Note
1	VX64-0001	VX- DL Adult Single Use P.C. Universal	<b>Adult DL</b>
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.	<b>Pediatric DL</b>
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	<b>Adult SL</b>
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.	<b>Pediatric SL</b>
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	<b>Pediatric DL w/ RD</b>
17	VX64-0017	VX-DL Ped. Autoclavable F.S. Kit 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	<b>Pediatric SL w/ RD</b>
20	VX64-0020	VX-SL Ped. Single Use 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, 09/05/2023**
**Name of Authorized Person**
**Ken Raichman, Director of QA & Regulatory Affairs**
