

# Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

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## DECLARATION OF CONFORMITY Medical Devices

We 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 August 11, 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 below, meet the provisions of the EC-Directive which apply to them:

The Ventilators 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 EGD is classified as class IIa, according to rule 10 per Annex IX of MDD 93/42/EEC amended by MDD 47/2007/EC.

Exhalation Valves, Pneumatic Connectors, Oxygen Blending Bags and Mixers, 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 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:

### **Manufacture:**

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

### **Authorized European Representative**

*Obelis S.A.  
BD Gal Wahis 53, 1030 Brussels  
BELGIUM*

### **Place and Date of issue**

*Petach Tikva, Israel, 13/11/2022*

### **Name of Authorized Person**

Ken Raichman, Director of QA & Regulatory Affairs

### **Signature**

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This declaration of conformity is valid until 31.12.2028

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Annex to the Declaration of Conformity EDEOC01 Rev Qe Updated 11/10/2020  
(Product List)

## PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by DEOC01 Rev Q 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:

	Description	Part Number	CE Certificate
1.	F60 PC DL Exhalation Valve	MEC-0034	Flight 60 / Flight 60T
2.	F60 Straight O2 Low-Flow Port Connector (5 pc)	SUB-0044	Flight 60 / Flight 60T
3.	F60 Elbow O2 Low-Flow Port Connector (5 pc)	SUB-0045	Flight 60 / Flight 60T
4.	F60 Internal Oxygen Supply Hose	SUB-0148	Flight 60 / Flight 60T
5.	F60 EGD Universal Kit	V60-80200-60	Flight 60 / Flight 60T
6.	Disposable Air Inlet Filters (5 pc)	V11-35300-60	Flight 60 / Flight 60T
7.	Air/Oxygen Mixer (3 m)	V13-00030-60	Flight 60 / Flight 60T
8.	Reusable Oxygen Blender Kit	V17-00000-67	Flight 60 / Flight 60T
9.	Single Use Oxygen Blending Bag Kit	V17-00001-67	Flight 60 / Flight 60T
10.	F50 PC Exhalation Valve	V54-00000-67	Flight 60 / Flight 60T
11.	F50/F60 Exhalation Valve Assy	V54-10100-67	Flight 60 / Flight 60T
12.	F60 SL Eng-Pad Ventilator Incl. Low Flow O2-Port	V60-0010/ 1010	Flight 60 / Flight 60T
13.	F60 SL Sym-Pad Ventilator Incl. Low Flow O2-Port	V60-0012/ 1012	Flight 60 / Flight 60T
14.	F60 DL Eng-Pad Ventilator Incl. Low Flow O2-Port	V61-0010/1010	Flight 60 / Flight 60T
15.	F60 DL Sym-Pad Ventilator Incl. Low Flow O2-Port	V61-0012/ 1012	Flight 60 / Flight 60T
16.	F60 DL Single Use Patient Circuit	V64-0010/ V64-50020-60	Flight 60 / Flight 60T
17.	F60 DL Flow Sensor Kit	V64-0012/ V64-50130-90	Flight 60 / Flight 60T
18.	F60 SL Flow Sensor Kit	V64-0013/ V64-50120-90	Flight 60 / Flight 60T
19.	F60 SL Single Use Ped PC	V64-0016 / V64-0020	Flight 60 / Flight 60T
20.	F60 SL Ped Autoclav PC RD	V64-0063/-PK	Flight 60 / Flight 60T
21.	F60 SL Ped SU PC RD	V64-0069/V64-0070	Flight 60 / Flight 60T
22.	F60 DL Single Use Ped PC	V64-0017/V64-0021	Flight 60 / Flight 60T
23.	DL Ped Autoclav PC RD	V64-0064/-PK	Flight 60 / Flight 60T
24.	F60 DL Ped Single Use PC RD	V64-0065/V64-0066	Flight 60 / Flight 60T
25.	F60 DL Ped Flow Sensor Kit	V64-0024 / V64-0025	Flight 60 / Flight 60T

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26.	F60 SL Autoclav Flow Sensor Kit	V64-0033 / -PK	Flight 60 / Flight 60T
27.	F60 DL Autoclav Flow Sensor Kit	V64-0034 / -PK	Flight 60 / Flight 60T
28.	F60 SL ped. Flow Sensor Kit	V64-0052 / V64-0053	Flight 60 / Flight 60T
29.	DL Ped Autoclav FS Kit RD	V64-0067 / V64-0068	Flight 60 / Flight 60T
30.	F60 Ped. SL FS Kit RD	V64-0059/-PK	Flight 60 / Flight 60T
31.	F60 Ped DL Flow Sensor Kit RD	V64-0058/-PK	Flight 60 / Flight 60T
32.	F60 SL Ped. Autoclav FS Kit RD	V64-0071 /V64-0072	Flight 60 / Flight 60T
33.	F60 SL Autoclavable PC	V64-0054/-PK	Flight 60 / Flight 60T
34.	F60 DL Ped Autoclav FS Kit	V64-0048/-PK	Flight 60 / Flight 60T
35.	F60 SL Ped. Autoclav FS Kit	V64-0047/-PK	Flight 60 / Flight 60T
36.	F60 SL Single Use PC	V64-50010-60 / V64-50110-90	Flight 60 / Flight 60T
37.	F60 DL Autoclavable PC	V64-0055/-PK	Flight 60 / Flight 60T
38.	F60 Dual Limb Diaphragm Silicon	V64-00050-90	Flight 60 / Flight 60T
39.	Flight 60 Ventilator (Flight 60, piston, SL, w Internal mixer)	V100-0001	Flight 60
40.	Flight 60 Ventilator (Flight 60, F60 SL Sym Internal Mixer)	V100-0001-PK	Flight 60
41.	Flight 60 Ventilator (Flight 60, piston, DL, w Internal mixer)	V100-0002	Flight 60
42.	Flight 60 Ventilator (Flight 60, F60 DL Sym Internal Mixer package)	V100-0002 -PK	Flight 60
43.	F60 SL ENG Internal Mixer	V100-0003 / -PK	Flight 60
44.	F60 DL ENG Internal Mixer	V100-0004 / -PK	Flight 60
45.	Flight 60 Ventilator (Flight 60 T, turbine, F60T SL w Internal mixer)	V200-0001	Flight 60T
46.	Flight 60 Ventilator (Flight 60 T, F60T SL Sym With Internal Mixer package)	V200-0001-PK	Flight 60T
47.	F60T SL ENG With Int Mixer-UM	V200-0001-UM / -PKU	Flight 60T
48.	Flight 60 Ventilator (Flight 60 T, turbine, F60T w Internal mixer)	V200-0002	Flight 60T
49.	Flight 60 Ventilator (Flight 60 T, F60T DL Sym w Internal Mixer package)	V200-0002-PK	Flight 60T
50.	F60T DL ENG Int Mixer-UM	V200-0002 -UM -PKU	Flight 60T
51.	Flight 60 Ventilator (Flight 60 T, turbine, F60T)	V200-0008	Flight 60T
52.	Flight 60 Ventilator (Flight 60 T, F60T DL Sym package)	V200-0008-PK	Flight 60T
53.	F60T DL ENG-UM	V200-0008-UM/-PKU	Flight 60T

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***Place and Date of Issue***

*Petach Tikva, Israel, 07/07/2024*

**Name of Authorized Person**

**Signature**

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Ken Raichman, Director of QA & Regulatory Affairs

Addendum

Flight 60T Basic UDI : 7290013641F60200DT