

Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

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, 24/12/20

Name of Authorized Person

Ken Raichman, Director of QA & Regulatory Affairs

Signature



This declaration of conformity is valid until 26.05.2024

Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

Annex to the Declaration of Conformity EDEOC01 Rev Qd 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 Autoclv 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 Autoclv 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

Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

Place and Date of Issue
Petach Tikva, Israel, 24/12/20

Name of Authorized Person
Ken Raichman, Director of QA & Regulatory Affairs

Signature



Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

Addendum to Declaration of Conformity (DoC)

This addendum refers to the Declaration of Conformity EDEOC01 Rev Qe, issued on December 24, 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 **7290013641F60200DT**:

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 Flight 60 and Flight 60T (reference number D1068300025) is valid until 2028-12-31.

3. Update the product list to remove obsolete items (no items were added):

	Description	Part Number	CE Certificate
1.	F60 PC DL Exhalation Valve	MEC-0034	Flight 60 / Flight 60T
2.	F60 Internal Oxygen Supply Hose	SUB-0148	Flight 60 / Flight 60T
3.	F60 EGD Universal Kit	V60-80200-60	Flight 60 / Flight 60T
4.	Disposable Air Inlet Filters (5 pc)	V11-35300-60	Flight 60 / Flight 60T
5.	Air/Oxygen Mixer (3 m)	V13-00030-60	Flight 60 / Flight 60T
6.	Reusable Oxygen Blender Kit	V17-00000-67	Flight 60 / Flight 60T
7.	Single Use Oxygen Blending Bag Kit	V17-00001-67	Flight 60 / Flight 60T
8.	F50/F60 Exhalation Valve Assy	V54-10100-67	Flight 60 / Flight 60T
9.	F60 DL Single Use Patient Circuit	V64-0010/ V64-50020-60	Flight 60 / Flight 60T
10.	F60 DL Flow Sensor Kit	V64-0012/ V64-50130-90	Flight 60 / Flight 60T
11.	F60 SL Flow Sensor Kit	V64-0013/ V64-50120-90	Flight 60 / Flight 60T
12.	F60 SL Single Use Ped PC	V64-0016 / V64-0020	Flight 60 / Flight 60T
13.	F60 DL Single Use Ped PC	V64-0017/V64-0021	Flight 60 / Flight 60T
14.	DL Ped Autoclv PC RD	V64-0064/-PK	Flight 60 / Flight 60T

Flight Medical Innovations Ltd.

Hatnufa 7, Petach Tikva, Israel

Place and Date of Issue
Petach Tikva, Israel, 24.05.25

Name of Authorized Person
Eyal Ozeri, Director of QA & Regulatory Affairs

Signature

A handwritten signature in blue ink, appearing to read "Eyal Ozeri".

This extend the validity of the declaration of conformity until 31.12.28