Airon
Part of the Inspiration Healthcare Group

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EU REGULATION 2023/607

MANUFACTURER'S DECLARATION

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates); and/or
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

General Product Name:	See attached Schedule
Legal Manufacturer:	Airon Corporation 751 North Drive Unit 6 Melbourne Florida 32934 USA
Legal Manufacturer SRN:	US-MF-000037861
EU Authorised Representative:	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands
EU Authorised Representative SRN:	NL-AR-000000116

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Notified Body:	Intertek Semko AB Box 1103 SE-164 22 Kista Sweden
Notified Body Number:	NB 0413
Directive Certificate Number(s) to Which This Confirmation is Made:	See attached schedule.
Original Expiry Date as Indicated on the Directive Certificate(s) Prior to the Extension of the Validity:	See attached schedule.
End Date of Extended Validity / Transition Period:	See attached schedule.

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We, as the manufacturer, declare under our sole responsibility:

- For the **Directive Certificate** listed in the attached schedule, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, *and*
- The listed **device(s)** in the attached schedule, and we as their manufacturer, are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate(s) as listed in the attached schedule:

- Directive Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- Expires *after* 20 March 2023:
    i. Formal application(s) to the Notified Body in accordance with Section 4.3, first subparagraph of Annex VII MDR for Conformity Assessment has been made by us to a Notified Body no later than 26 May 2024 for the device(s) listed in the attached schedule or their substitute(s) and signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System (QMS):

- A QMS in accordance with Article 10(9) MDR is in place.

Device(s) as listed in the attached schedule:

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

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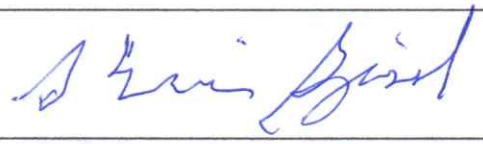
Name:	G. Eric Gjerde
Title:	President & CEO
Signature:	
Place of Issue:	751 North Dr STE 6, Melbourne, FL 32934, USA
Date of Issue:	January 2, 2024

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1. APPENDIX 1 – SCHEDULE OF DEVICES

The above Manufacturer's Declaration is valid for the following devices:

Identification of the Device(s) (e.g. Device Name, Family/Group Name Device Model, or Catalogue Number)	Directive Certificate Number(s)	Original MDD Expiry Date as Indicated on the Directive Certificate(s)	Notified Body Name and Number That Issued the Directive Certificate	Notified Body Name and Number Where the MDR Application was Lodged / Contract Signed	End Date of Extended Validity / Transition Period	Substitute Device(s)
Mobile Ventilators - pNeuton Ventilator Model S (20001) - pNeuton Ventilator Model S (20002) - pNeuton Ventilator Model S (20013) - pNeuton Ventilator Model S (20014) - pNeuton Ventilator Model Mini (20031) - pNeuton Ventilator Model Mini (20033) - pNeuton Ventilator Model Mini neo (20041) - pNeuton Ventilator Model Mini neo (20042) - pNeuton Ventilator Model A (20051) - pNeuton Ventilator Model A (20052) - pNeuton Ventilator Model A (20056) - pNeuton Ventilator Model A (20057)	41315697-02	26 May 2024	Intertek Semko AB (0413)	Intertek Semko AB (0413)	31-DEC-28	N/A
CPAP Systems MACS CPAP System (20201) MACS CPAP System (20212) MACS CPAP System (20213)	41315697-02	26 May 2024	Intertek Semko AB (0413)	Intertek Semko AB (0413)	31-DEC-28	N/A

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Identification of the Device(s) (e.g. Device Name, Family/Group Name Device Model, or Catalogue Number)	Directive Certificate Number(s)	Original MDD Expiry Date as Indicated on the Directive Certificate(s)	Notified Body Name and Number That Issued the Directive Certificate	Notified Body Name and Number Where the MDR Application was Lodged / Contract Signed	End Date of Extended Validity / Transition Period	Substitute Device(s)
Patient Breathing Circuits - Patient circuit, disposable, adult/pediatric with CPAP mask, headstrap 1.8m long (58001) - Patient circuit, disposable, adult/pediatric with CPAP large mask, headstrap 1.8m long (58011) - Patient circuit, disposable, adult/pediatric with CPAP large mask, expiratory filter, headstrap 1.8m long (58021) - Patient circuit, Neonatal/Infant, disposable, 10mm ID 1.8m long (58031) - Patient circuit, Neonatal/Infant, disposable, 10mm ID 2.4m long (58201) - Patient circuit, Child/Pediatric, disposable, 15mm ID 1.8m long (58035) - Patient circuit, disposable, adult/pediatric 2.4m long (58051) - Patient circuit, reusable adult/pediatric 1.5m long (58301)	41315697-02	26 May 2024	Intertek Semko AB (0413)	Intertek Semko AB (0413)	31-DEC-28	N/A

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Oxygen Supply Accessories - Regulator, Oxygen, Pin index style, High Pressure, MRI compatible (21051) - Regulator, Medical Air, Pin index style, High Pressure, MRI compatible (21052) - High pressure Oxygen hose, 0.9m long, green(21061) - High pressure Medical Air hose, 0.9m long, yellow (21062) - High pressure Medical Air hose, 2.4m long, yellow (21065) - High pressure Oxygen hose, 2.4m long ISO white, DISS one end only, MRI compatible (21067) - High pressure Oxygen hose, 2.4m long, green (21068) - High pressure Oxygen hose, 0.9m long, green (21069) - High pressure Medical Air hose, 2.4m long, ISO black w/white striping, DISS connector on one end (21070) - Cylinder, Oxygen, USA "E" size (650L) MRI compatible (21071) - Cylinder, Medical Air, USA "E" size (650 L) MRI compatible (21072) - High pressure Oxygen hose, 3.7m long, green (21082) - High pressure Oxygen hose, 0.5m long ISO white, DISS one end only, MRI compatible (21086) - High pressure Medical Air hose, 0.5m long, ISO black w/white striping, DISS connector on one end (21087) - High pressure Oxygen hose, 3.0m long ISO white, DISS one end only, MRI compatible (21088) - High pressure Medical Air hose, 3.0m long, ISO black w/white striping, DISS connector on one end (21089)	41315697-02	26 May 2024	Intertek Semko AB (0413)	Intertek Semko AB (0413)	31-DEC-28	N/A

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General Accessories - Stand, Mobile, Models A, S, MRI Compatible (21001) - Stand, Mobile, Mini MRI compatible (21005) - Bed rail mount, Model A (21016) - Bed rail mount, Model S (21017) - Pole mount, Mini ventilator (21018) - Remote Alarm (21031) - Remote Alarm Cable, male/female ends 15.24m long (21035) - Remote Alarm Cable, male/female ends 30.48m long (21036) - Bracket, pole mount, MACS (21040) - Bracket, bed rail mount, MACS (21041)	41315697-02	26 May 2024	Intertek Semko AB (0413)	Intertek Semko AB (0413)	31-DEC-28	N/A