Airflo (Xiamen) Medical Co., Ltd
4F, No. 6, East Haijian Road, Haicang, Xiamen,
Fujian, China

Tel: 86-592-6890831 Fax: 86-592-6895050

CE
0197

EC DECLARATION OF CONFORMITY

For the following equipment：

Alternating-Pressure Mattress System

Pump:
Aries Series, Libra Series, Leo Series, Taurus Series, Aquarius Series, Scorpio Series, Virgo. Series, Gemini Series, Pisces Series, Capricorn Series

Mattress:
EFFECT 10421, EFFECT 10422, EFFECT 10423,
EFFECT 8410, EFFECT 8210, EFFECT 5412, EFFECT 5400

Cushion:
SEAT CUSHION

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning Medical Devices Directive（93/42/EEC）and amended by （2007/47/EC）with the compliance of the essential requirements – Annex I and the conformity assessment Annex II excluding section 4 (Module H) to be certified by TUV Rheinland (ID: 0197)

For the evaluation regarding the **Class IIa** (per ***Rule 9*** *in part III, Annex IX of the Directive 93/42/EEC*) product safety aspects, the following standards were applied：

- *EN 980:2008 Symbols for use in the labelling of medical devices*
- *EN 1041:2008 Information supplied by the manufacturer of medical devices*
- *EN 1122B:2001 Plastics. Determination of cadmium. Wet decomposition method*
- *EN ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*
- *EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*
- *EN ISO 10993-10:2014 Biological evaluation of medical devices -- Part 10: Tests per Annex VII of 93/42/EEC*

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for irritation and skin sensitization

- *EN ISO 13485: 2016 Medical Device- Quality management systems*-Requirements for regulatory purposes
- *EN ISO 14971:2012 Medical devices - Application of risk management to medical devices*
- *EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements.*
- *EN 60601-1:2006+A1:2013 / IEC 60601-1:2005+A1:2012 Medical electrical equipment. General requirements for basic safety and essential performance*
- *EN 60601-1-11:2015 / IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
- *EN 60601-1-2:2015 / IEC 60601-1-2:2014 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests*
- *IEC 62366:2007+A1:2014 Medical devices — Part 1: Application of usability engineering to medical devices*
- *EC Certificate Registration No.: HD 2089655-1*

The following representative in Europe is responsible for this declaration：

Emergo Europe

（Representative Name）

Prinsessegracht 20 2514 AP The Hague The Netherlands

（Representative Address）

Person responsible for making this declaration：

Airflo (Xiamen) Medical Co., Ltd.

（Manufacturer Name）

1F,3F,4F,No.6,East Haijing Road, Haicang, Xiamen, Fujian Province 361026, P.R.C.

（Manufacturer Address）

General Manager / Mr. Charles Chiu Charles Chiu *03/15/ 2021*

（Position / Title） （Legal Signature） （Date）