Grand Healthcare Co., Ltd.
4F, No.49, Sec.2, Jen Ai Road, Taipei, Taiwan

Tel: 886-2-23221652 Fax: 886-2-23576802

CE

EC Declaration of Conformity

General applicable regulation：

Medical Device Regulation：MDR (EU) 2017/745
Council regulation 2017/745 of 5 April 2017 concerning medical devices

Name of the Manufacturer：
Airflo (Xiamen) Medical Co., Ltd.
Address of the Manufacturer：
4F, NO.6, East Haijing Road, Haicang, Xiamen, Fujian, China

Name of the authorized representative of European Union:
Emergo Europe
Address of the authorized representative of European Union:
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Product: Alternating Pressure Pump with Mattress
820000300 MED AIRE FlexWave
Basic UDI-DI : 697291060APMQV (Alternating Pressure Mattress)

Classification: Class I (MDR, Annex VIII) Rule 1: All non-invasive devices are in Class I,

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

- Regulation (EU) 2017/745, on Medical Devices (MDR)
- Regulation (EC) No. 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Standards：
EN ISO 14971:2019 •EN ISO 13485:2016

All applicable harmonized Standards (published in the Official Journal of the European Communities)

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General Manager of Grand Healthcare Co., Ltd.

Charles Chiu Date: 2023-1-31