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Airflo (Xiamen) Medical Co., Ltd.

*Care With You In Mind*

4F, NO.6, EAST HAIJIAN RD., HAICANG, XIAMEN, FUJIAN, CHINA

Tel: 86-592-689-0831

Fax: 86-592-689-5050



## EU DECLARATION OF CONFORMITY

**Name of the Manufacturer:** Airflo (Xiamen) Medical Co., Ltd.

**Address of the Manufacturer:** 1F, 3F, 4F, No. 6, East Haijing Road, Haicang Xiamen, Fujian, China

**EN ISO 13485 Certificate Registration No. :** SX 2089655-1

**GCP:** 697291060

**GLN:** 6972910600011

**SRN:** CN-MF-000008552

**Name of the authorized representative of European Union:** Emergo Europe B.V.

**Address of the authorized representative of European Union:** Prinsessegracht 20 2514 AP The Hague The Netherlands

**SRN:** NL-AR-000000116

**This declaration of conformity is issued under the sole responsibility of the manufacturer.**

**Product:** Water Mattress

**Product - instrument Type / Model:** Effect 100

**Description and function designation:** for the prevention and treatment of pressure ulcers

**Classification of the product as the medical device:**

Class I Noninvasive devices, according to annex VIII of Government Order MDR 2017/745-rule 1

**Basic UDI-DI:** 697291060WM3B

**We herewith declare that the above-mentioned product is in conformity with the relevant Union harmonization legislation:**

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

**Authorized Signature:**

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Charles Chiu  
General Manager of  
Airflo (Xiamen) Medical Co., Ltd.

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Place and date of declaration issue:  
Airflo (Xiamen) Medical Co., Ltd.  
2020/8/4