
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

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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:

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

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