Airflo(Xiamen)MedicalCo.,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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CE

EU DECLARATION OF CONFORMITY

Name of the Manufacturer: Airflo (Xiamen) Medical Co., Ltd.
Address of the Manufacturer: 4F, NO.6, East Haijian Road, Haicang, Xiamen, Fujia, China
Certificate Registration No. : HD 2089655-1
GCP: 697291060
GLN: 6972910600011
Name of the authorized representative of European Union: Y. Sung Handelsvertretung
Address of the authorized representative of European Union: Duesselthaler Str.24, 40211 Duesseldorf Germany
This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product: Alternating Pressure Mattress System
Product - instrument Type / Model: L803 & L839
Description and function designation: For the prevention and treatment of bedsores
Classification of the product as the medical device:
Classification (According to the Annex VIII of MDR): Class I.
Rule: According to rule 13, Annex VIII, Chapter III of Medical Device Regulation (UE)2017/745.
Conformity Assessment procedure: Annex II and III of MDR
Basic UDI-DI: 697291060APMQV

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)
- Directive 2011/65/EU, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared:
EN 60601-1:2014, EN 60601-1-2:2015, EN 60601-1-11:2015, EN ISO14971:2012

Authorized Signature:

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

Place and date of declaration issue:
Airflo (Xiamen) Medical Co., Ltd.
2021/5/12