



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

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



## 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: Gel Cushion

D-Q SiT Gel: 820200200,820200210,820200220,820200230,820200240

Basic UDI-DI : 697291060PRCSS (Pressure Relief Cushion)

Classification: Class I (MDR, Annex VIII) Rule: 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.

A handwritten signature in black ink, appearing to read 'Charles Chiu', written in a cursive style.

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Charles Chiu

Date: 2023-1-31