



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:

**Share Info GmbH**

**Address of the authorized representative of European Union:**

**Am Schulzentrum 12, 41564 Kaarst, Germany**

Product: Gel Cushion

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

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

Intended purpose: The purpose of antidecubitus seat cushions is to reduce local mechanical weight loading and to mitigate known risk factors which promote the development of pressure sore. This is based on the principle of pressure distribution. The pressure will be distributed over the largest possible area and when sitting, pressure on the individual parts will be reduced.

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.

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Charles Chiu

Date: 2025-6-17