湖北省潜江市江赫醫用材料有限公司
HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO, LTD

Declaration of Conformity

Manufacturer:
Hubei Qianjiang Kingphar Medical Material Co., Ltd.
Yuanguang Road, 433100Qianjiang, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000009051

European representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
SRN: DE-AR-000000001

Switzerland Representative:
CMC Medical Devices GmbH
Bahnhofstrasse 32, CH-6300 Zug, Switzerland

Product name: Adhesive Wound Dressing
Trade name: Catheter fixing dressing
Model number: AWD-NW-II
EMDN Code: M04010101
Basic UDI-DI: 694878812013Q4
Intended use: Adhesive Wound Dressing is used for various wound care such as exudate absorption, cleaning care, and so on.
Classification (MDR(EU)2017/745, Annex VIII): IIa, Annex VIII Rule 4.
Conformity Assessment Route: Annex XI Part A Section 10.
Applied Standard: EN13726-1:2002, EN13726-2:2002, EN13726-3:2003

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following Regulation(EU)2017/745 on Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

REGULATIONS
Medical Device Regulation(MDR):REGULATION (EU)2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017.
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MÜnchen, Germany
NB Identification number: 0123
(EC) Certificate(s): G20 045790 0031 Rev. 01
Expire date of the Certificate: 2027-11-14
Start of CE Marking: Yes

Signature:
Name: Wang Zhongxiao
Position: President
Place: Qianjiang, Hubei, PRC
Date: 2024-08-22

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Revision: 02.168.00