



EU Declaration of Conformity

Manufacturer:

Hubei Qianjiang Kingphar Medical Material Co., Ltd.
Yuanguang Road, 433100 Qianjiang, 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

Product name: Dressing Kit

Trade name: Dressing Kit

Model number: 08/02/PEG/GHC; 08/02/VS/GHC.

EMDN Code: T0203

Basic UDI-DI: 694878812012Q2

Intended use: Dressing kit is designed for immediate use in the OR, It can also be applied to the treatment of trauma in home and hospital settings, such as cleaning, disinfecting, and dressing various wounds.

Classification (MDR(EU)2017/745 , Annex VIII): IIa, Annex VIII Rule 6.

Conformity Assessment Route: Annex XI Part A Section 10.

Applied Standard: EN ISO 13485:2016+A11:2021, EN 14079:2003, EN 13726:2023, EN 1644-1:1997, EN ISO14971:2019, ISO15223-1:2021/Amd.1:2025, ISO11737-1:2018, ISO11737-2: 2019, ISO11607-1: 2019.

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: 2026-04-10

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

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