



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

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: Sterile Elastic Bandage

Trade name: sterile bandage

Model number: 1230310201K, 1230310202K, 1230310203K, 1230310204K, 1230310205K, 1230113062K, 1230113042K, 1230113052K

EMDN Code: M0303010101

Basic UDI-DI: 694878811*007E8

Intended use: Sterile Elastic Bandage is widely used for bandaging, fixing, binding and hemostasis of injured parts.

Classification (MDR(EU)2017/745, Annex VIII): Is, Annex VIII Rule 4

Conformity Assessment Route: Annex XI Part A Section 10.

Applied Standard: BP 2023.

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



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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): G21 045790 0032 Rev. 00

Expire date of the Certificate: 2029-03-04

Start of CE Marking: Yes

Signature:

Name: Wang Zhongxiao

Position: President

Place: Qianjiang, Hubei, PRC

Date: 2024-07-01

Revision: 01

Hubei Qianjiang Kingphar Medical Material Co., Ltd.

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