



EU 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

Product Name: Absorbent Gauze (Cutting, Folded or Rolled)

EMDN Code: M0201020102

BASIC UDI-DI: 694878811018Q7

Intended use: Absorbent Gauze (Cutting, Folded or Rolled) are widely used for bandaging, fixing, binding and hemostasis of injured parts.

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

Conformity Assessment Route: Article 19, Annex II and Annex III.

Applied Standard: EN 14079:2003.

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

REGULATION (EU)2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
OF 5 April 2017.

Signature:

Name: Wang Zhongxiao

Position: President

Place: Qianjiang, Hubei, PRC

Date : 2023-06-07

Revision: 03

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