

## 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  
**SRN:** DE-AR-000000001

**Product name:** Sterile Gauze ball without X-Ray

**Model number:**

Art.No.	Trade name	Class
9016007	Askina@Schlinggazetupfer sterile	Is
9016015	Askina@Schlinggazetupfer sterile	Is

**EMDN Code:** M0201020101

**Basic UDI-DI:** 694878811\*006E6

**Intended use:** Sterile Gauze ball without X-Ray is a human medical dressing used for the treatment of wounds like cleaning wounds, absorbing blood and exudates around wound and isolating wounds against infection.

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

Conformity Assessment Route: Annex XI Part A Section 10.

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**

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

Effective date of the Certificate: 2024-03-05

Expire date of the Certificate: 2029-03-04

Start of CE Marking: Yes

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

Signature: 

Name: Wang Zhongxiao

Position: President

Place: Qianjiang, Hubei, PRC

Date: 2024-03-05

Revision: 00

**Effective**

Hubei Qianjiang Kingphar Medical Materials Co. Ltd