



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: Dental Cotton roll

Model Number: 7101N1

EMDN:M010102

BASIC UDI-DI: 694878811026Q6

Intended use:Dental Cotton roll,non-sterile is widely used as a saliva absorber and intended to absorb moisture from the oral cavity during dental procedures.

Classification (MDR(EU)2017/745 , Annex VIII): I, Annex VIII Rule 5

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

Applied Standard & Common Specification: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.

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,P.R.C

Date:2021.12.10