

Doc. No.	KSX/TD-GRN-017-104	Title	EU Declaration of Conformity of Nonsterile Gauze Rolls		
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## EU Declaration of Conformity

**Manufacturer Name:** Kingstar Medical (Xianning) Co., Ltd.

**Manufacturer Address:** No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China.

**Location of Manufacturer:** Xianning City, Hubei Province, China.

**Authorized Representative:** Shanghai International Holding Corp. GmbH (Europe)

**Address of their Registered Place of Business:** Eiffestrasse 80, D-20537, Hamburg, Germany

**Location be established:** Germany

**Registered Trade Name / Mark:** Kingstar

**Name of the device:** Nonsterile Gauze Rolls

**CND Code:** M020106, GAUZES, PATCHES/ROLLS

**UMDNS Code:** 11327, Dressings, Roller Gauze

**Basic UDI-DI:** 6971872201071000MN

**Intended Purpose:** Typically designed for a variety of applications (non-dedicated) such as a primary wound dressing, dressing retention, injury padding and compression.

**Risk Class of the Device:** Class I, based on Rule 4 of Annex VIII of the Regulation (EU) 2017/745.

*All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: — class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;*

**The Conformity Assessment Procedure Performed:** According to Article 19 of the Regulation (EU) 2017/745, draw up this EU declaration of conformity which contain the information set out in Annex IV of the Regulation (EU) 2017/745.

**CS used or Standard applied:** EN 14079:2003

**Identification of the device:** Please see Appendix 1

**Declaration:** This declaration of conformity is issued under the sole responsibility of Kingstar Medical (Xianning) Co., Ltd. We hereby declare that the medical device specified above meet the provision of the Regulation (EU) 2017/745. This declaration is supported by the quality system approval to ISO 13485 by TÜV SÜD Product Service GmbH.

All supporting documentation is retained at the premises of the manufacturer.


**Signed for and on behalf of:**

Place of Issue: Xianning City, Hubei Province, China.

Date of Issue: 2020.04.30

Print Name: Yuanqiang Ren

Function: Management Representative

Signature: 

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Appendix 1 --- **Identification of the device:****Nonsterile Gauze Rolls**

No.	Catalogue Number	Specification	Packaging Configuration
1	Mat. 9175831	40'sx40's, 17th, 5cm x 50m, roll	1roll/bag, 36bags/case
2	Mat. 9174951	40'sx40's, 17th, 7.5cm x 50m, roll	1roll/bag, 24bags/case
3	Mat. 9173261	40'sx40's, 17th, 10cm x 50m, roll	1roll/bag, 18bags/case
4	Mat. 205140/1	40'sx40's, 17th, 120cm x 100m, in pieces	10 pieces/case
5	Mat. 205141/1	40'sx40's, 17th, 120cm x 10m, in pieces	25 pieces/case