

Doc. No.	KSX/TD-GBDN-017-104	Title	EU Declaration of Conformity of Nonsterile Gauze Bandages		
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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:** Eifestrasse 80, D-20537, Hamburg, Germany

**Location be established:** Germany

**Registered Trade Name / Mark:** Kingstar

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

**CND Code:** M030101, BANDAGES, COTTON GAUZES

**UMDNS Code:** 10281, Bandages, Gauze

**Basic UDI-DI:** 6971872201081000MZ

**Intended Purpose:** Used to bind up surgical dressings and patient's body.

**Risk Class of the Device:** Class I, based on Rule 1 of Annex VIII of the Regulation (EU) 2017/745.

**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 find in Annex I.

**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.

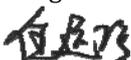
**Signed for and on behalf of:**

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:**
**1. Nonsterile Gauze Bandages (SELVEDGE GAUZE BANDAGES, 32'sx32's, 26x20)**

No.	Catalogue Number	Specification	Packaging Configuration
1	Mat. 7410181	1cm x 5m, individual pack	2,400 rolls/case
2	Mat. 7420181	2cm x 5m, individual pack	1,600 rolls/case
3	Mat. 7430181	3cm x 5m, individual pack	1,600 rolls/case
4	Mat. 7440181	6cm x 5m, individual pack	1,200 rolls/case
5	Mat. 7450181	10cm x 5m, individual pack	1,200 rolls/case
6	Mat. 7460181	15cm x 5m, individual pack	1,200 rolls/case
7	Mat. 8163181	1cm x 5m, bulk	4,000 rolls/case
8	Mat. 8164181	2cm x 5m, bulk	2,400 rolls/case
9	Mat. 8165181	3cm x 5m, bulk	2,000 rolls/case
10	Mat. 8166181	6cm x 5m, bulk	1,200 rolls/case
11	Mat. 8167181	10cm x 5m, bulk	1,200 rolls/case
12	Mat. 8168181	15cm x 5m, bulk	1,200 rolls/case

**2. Nonsterile Gauze Bandages (W.O.W. BANDAGES, 40'sx40's, 25.5x18)**

No.	Catalogue Number	Specification	Packaging Configuration
1	Mat. 62051170	15cm x 5m	100 rolls/case

**3. Nonsterile Gauze Bandages (W.O.W. BANDAGES, 40'sx40's, 24x15)**

No.	Catalogue Number	Specification	Packaging Configuration
1	Mat. 8169183	6cm x 5m	200 rolls/case
2	Mat. 8170183	10cm x 5m	200 rolls/case
3	Mat. 8171183	15cm x 5m	200 rolls/case