

Doc. No.	KSX/TD-GSN-017-104	Title	EU Declaration of Conformity of Nonsterile Gauze Sponges		
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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 Sponges

CND Code: M0201, COTTON GAUZES

UMDNS Code: 13700, Sponges, Gauze

Basic UDI-DI: 6971872201011000KL

Intended Purpose: Applied on the intact skin and near the patient's wound to absorb exudate.

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 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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Annex I --- Identification of the Device Covered by the EU Declaration of Conformity

Identification of the Device

Table --- Identification of the Device

No.	Catalogue Number	Specification	Packaging Configuration
1	Mat. 205130/1	40'sx40's, 17threads, 5x5cm, 12ply	400 pcs/bag, 10 bags/case
2	Mat. 205131/1	40'sx40's, 17threads, 5x5cm, 16ply	400 pcs/bag, 10 bags/case
3	Mat. 205132/1	40'sx40's, 17threads, 5x10cm, 16ply	400 pcs/bag, 10 bags/case
4	Mat. 205133/1	40'sx40's, 17threads, 7.5x7.5cm, 16ply	400 pcs/bag, 4 bags/case
5	Mat. 205134/1	40'sx40's, 17threads, 10x10cm, 16ply	200 pcs/bag, 10 bags/case
6	Mat. 205135/1	40'sx40's, 17threads, 10x12.5cm, 16ply	200 pcs/bag, 6 bags/case
7	Mat. 205136/1	40'sx40's, 17threads, 7.5x10cm, 16ply	200 pcs/bag, 10 bags/case