

Doc. No.	KSW/TD-TBNN-017	Title	EU Declaration of Conformity of Non-woven Triangular Bandages		
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EU Declaration of Conformity

Manufacturer Name: Kingstar Industries (Wuhan) Co., Ltd.

Manufacturer Address: No.5 Xiaoxiangxi Road, Jinyinhu, Dongxihu District, Wuhan, Hubei, China, 430040

Location of Manufacturer: Wuhan 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

Basic UDI-DI code: 6973554891271000X4

Registered Trade Name / Mark: Kingstar

Name of the device: Non-woven Triangular Bandages

CND Code: M030102, NON-WOVEN BANDAGES

UMDNS Code: 15203, bandages, other

Intended Purpose: Intend for binding up wound dressings or injured head, shoulder, chest, elbow, or wrist etc., holding them in place, and helping support injured body parts.

Risk Class of the Device: Class I, based on Rule 1 of ANNEX VIII of 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: DIN 13168-D: 1989 Surgical Dressings: Triangular Bandage

Identification of the device: Please find in Annex I

Declaration: This declaration of conformity is issued under the sole responsibility of Kingstar Industries (Wuhan) Co., Ltd. We hereby declare that the medical device specified above meet the provision of the Regulation (EU) 2017/745 for medical device. 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: Wuhan City, Hubei Province, China.

Date of Issue: 2020-02-28

Print Name: Aiqun Zhou

Function: Management Representative

Signature: 

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

1. Identification of the Device

Table --- Identification of the Device

No.	WERO REF	Kingstar Article Number	Specification	Packaging Configuration
1	230317	5142360010	Triangular bandages, White, 136 x 96 x 96cm	1 pc/foil bag, 400 bags/case

2 Photograph of Non-woven Triangular Bandages



Photo 1 --- Non-woven Triangular Bandages in foil bag



Photo 2 --- Non-woven Triangular Bandages