

Doc. No.	KSW/TD-EBN-017	Title	EU Declaration of Conformity of NonSterile Elastic 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: 6973554891151000VZ

Registered Trade Name / Mark: Kingstar

Name of the device: Nonsterile elastic bandages

CND Code: M030301, ELASTIC BANDAGES, FIXING

UMDNS Code: 10279, Bandages, Elastic

Intended Purpose: Intended to be wrapped around a part of the body to secure a device/dressings to the patient, without adhering to the body.

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 61634: 1993 Fixierbinde – Immobilising bandage

Identification of the device: Please find in Annex I

Declaration: This declaration of conformity is issued under the sole responsibility 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:

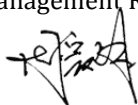
Place of Issue: Wuhan City, Hubei Province, China.

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	91015	5116340030	Elastic bandage, 4cm x 4m	1 roll/foil bag, 1,500 bags/case
2	91020	5116340070	Elastic bandage, 4cm x 4m	1 roll/foil bag, 10bags/box, 192 boxes/case
3	91016	5116340040	Elastic bandage, 6cm x 4m	1 roll/foil bag, 1,250 bags/case
4	91021	5116340080	Elastic bandage, 6cm x 4m	1 roll/foil bag, 10bags/box, 120 boxes/case
5	91018	5116340050	Elastic bandage, 8cm x 4m	1 roll/foil bag, 1,000 bags/case
6	91022	5116340090	Elastic bandage, 8cm x 4m	1 roll/foil bag, 10bags/box, 120 boxes/case
7	91019	5116340060	Elastic bandage, 10cm x 4m	1 roll/foil bag, 800 bags/case
8	91023	5116340100	Elastic bandage, 10cm x 4m	1 roll/foil bag, 10bags/box, 96 boxes/case

2 Photograph of Nonsterile Elastic Bandages



Photo 1 --- Nonsterile Elastic Bandages in foil bag



Photo 2 --- Nonsterile Elastic Bandages