

Doc. No.	KSW/TD-SABN-017	Title	EU Declaration of Conformity of NonSterile Self-adhesive Bandages		
Ver./Rev.No.	A/0	Issued Date	2020.02.28	Page/Total	1 / 2

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: Eifflstrasse 80, D-20537, Hamburg, Germany

Location be established: Germany

Basic UDI-DI code: 6973554891171000WP

Registered Trade Name / Mark: Kingstar

Name of the device: Nonsterile Self-adhesive Bandages

CND Code: M03040202, ELASTIC SUPPORT BANDAGES, COHESIVE

UMDNS Code: 10288, Bandages, Self-Adherent

Intended Purpose: Intended to be wrapped around a part of the body to secure a device (e.g., skin dressing, catheter, cannula) to the patient, without adhering to or compressing 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: N/A

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:

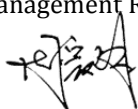
Place of Issue: Wuhan City, Hubei Province, China.

Date of Issue: 2020-02-28

Print Name: Aiqun Zhou

Function: Management Representative

Signature:



Doc. No.	KSW/TD-SABN-017	Title	EU Declaration of Conformity of NonSterile Self-adhesive Bandages		
Ver./Rev.No.	A/0	Issued Date	2020.02.28	Page/Total	2 / 2

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	201029	5142370010	Self-adhesive Bandage, 3cm x 5.5m	1 pcs/foil bag, 250 bags/case
2	201030	/	Self-adhesive Bandage, 3cm x 5.5m	2 Stk/Pkg
3	201031	/	Self-adhesive Bandage, 3cm x 5.5m	12 Stk/Pkg

2 Photograph of Nonsterile Self-adhesive Bandages



Photo 1 --- Nonsterile Self-adhesive Bandages in foil bag



Photo 2 --- Nonsterile Self-adhesive