

Doc. No.	KSW/TD-EBKN-017	Title	EU Declaration of Conformity of NonSterile Emergency Blanket		
Ver./Rev.No.	A/1	Issued Date	2022.04.01	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: Eiffestrasse 80, D-20537, Hamburg, Germany

Location be established: Germany

Registered Trade Name / Mark: Kingstar

Name of the device: Nonsterile Emergency Blanket

CND Code: N/A

UMDNS Code: 10416, Blankets, Aluminized Rescue

Basic UDI-DI code: 6971872201281000NT

Intended Purpose: Intend to keep a person warm and to prevent the further loss of body heat in an emergency rescue situation. It is typically used by emergency medical services (EMS) or first aid. **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 13164: 2014-01 **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: 2022.04.01 Print Name: Jun Liu

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 REF	Specification	Packaging Configuration
1	210186	A040003	Emergency blanket, green , 160 x 210cm	1 pc/foil bag, 300 bags/case
2	210120		Emergency blanket, gold / silver, 160 x 210cm	1 pc/ minigri bag, 250 bags/case

2 Photograph of Nonsterile Emergency Blanket







Photo 1 --- Emergency Blanket in PE bag

Photo 2 --- Emergency Blanket - Fold, & wrapped