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: 6973554891001000TV
Registered Trade Name / Mark: Kingstar
Name of the device: Nonsterile Non-woven Sponges
CND Code: M0202030102, NON-WOVEN SPONGES, NOT RX, NOT STERILE
UMDNS Code: 13703, Sponges, Rayon Cellulose

Intended Purpose: The Nonsterile Non-woven Sponge is an external use nonsterile device intended for clean and absorb body-surface exudates near wounds.
Risk Class of the Device: Class I, based on Rule 4 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: EN 1644-1: 1997, and EN 1644-2: 2000
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: 2020-09-11
Print Name: Aiqun Zhou
Function: Management Representative
Signature:

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	260074	5142110010	200mm x 300mm	5 pcs/ PE bag, 500 bags/case

2 Photograph of Nonsterile Non-woven Sponges

Photo 1 --- Nonsterile Non-woven Sponges in bags

Photo 2 --- Non-woven Sponges