EU Declaration of Conformity

Manufacturer Name: Kingstar Medical (Xianning) Co., Ltd.
Manufacturer Address: No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China
SRN of the Manufacturer: CN-MF-000006015
Location of Manufacturer: Xianning City, Hubei Province, China.
Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
SRN of the Authorized Representative: DE-AR-000000001
Address of their Registered Place of Business: Eiffestraße 80, 20537 Hamburg, Germany
Location be established: Germany

Basic UDI-DI code: 6971872201151000MD
Name of the device: Nonsterile Elastic Bandages
EMDN Code: M03030101, Elastic Fixing Bandages, Non-Adhesive
UMDNS Code: 10279, Bandages, Elastic
GMDN Code: 10284, Pressure bandage, non-latex, single-use

Intended Purpose: Intended to be wrapped around a part of the body to secure a device to the patient, without adhering to or compressing the body. It is used in various clinical specialties (e.g., dermatology, general, plastic surgery).

Risk Class of the Device: Class I, based on Rule 4 of ANNEX VIII of Regulation (EU) 2017/745.

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates.

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 II and III of the Regulation (EU) 2017/745.

Identification of the device: Please find in Annex I

CS used or Standard applied: Please find in Annex II.

Declaration: This declaration of conformity is issued under the sole responsibility of Kingstar Medical (Xianning) 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.

Notified Body: TÜV SÜD Product Service GmbH
Address: Ridlerstr. 65, 80339 Munich, Germany
Identification No.: CE0123

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2024-08-30
Print Name: Fan Rong
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 REF	Kingstar Art. Nr.	Product name	Specification	Packaging configuration
1	91015	C034012	5116340030	Nonsterile Elastic Bandages	4 cm × 400 cm	1 roll/foil bag, 1500 rolls/carton
2	91020		5116340070		4 cm × 400 cm	1 roll/foil bag, 10 rolls/box, 192 boxes/carton
3	91016	C034010	5116340040		6 cm × 400 cm	1 roll/foil bag, 1250 rolls/carton
4	91021		5116340080		6 cm × 400 cm	1 roll/foil bag, 10 rolls/box, 120 boxes/carton
5	91018	C034011	5116340050		8 cm × 400 cm	1 roll/foil bag, 1000 rolls/carton
6	91022		5116340090		8 cm × 400 cm	1 roll/foil bag, 10 rolls/box, 120 boxes/carton
7	91019	C034013	5116340060		10 cm × 400 cm	1 roll/foil bag, 800 rolls/carton
8	91023		5116340100		10 cm × 400 cm	1 roll/foil bag, 10 rolls/box, 96 boxes/carton

2. Photograph of Nonsterile Elastic Bandages

Photo 1 --- Elastic Bandages in nonsterile packaging

Photo 2 --- Nonsterile Elastic Bandages

Annex II --- European Harmonization and International Standard list

Category	No.	Standards	Content
QMS	1	EN ISO 13485:2016/A11:2021	Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)
Labeling	2	ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part1: General requirements
	3	EN ISO 20417: 2021	Medical devices- Information to be supplied by the manufacturer (ISO 20417:2021)
Risk management	4	EN ISO 14971:2019/A11:2021	Medical devices-Application of risk management to medical devices (ISO 14971:2019)
Usability	5	IEC 62366-1:2015/A1:2020	Medical devices-Application of usability engineering to medical devices
Clinical Evaluation	6	MEDDEV 2.7.1 rev 4	Guidance document for clinical evaluation

Sampling Inspection	7	ISO 2859-1:1999/A1:2011	Sampling procedures for inspection by attributes--Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
Transportation	8	ISTA 2A: 2011	Partial simulation performance test procedure
PMS	9	MEDDEV 2.12-1:2013	Guidelines on a medical devices vigilance system
PSUR	10	ISO/TR 20416: 2020	Medical devices - Post-market surveillance for manufacturers
Environment	11	EN ISO 14644-1: 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
	12	EN ISO 14644-2: 2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
	13	EN ISO 14644-3: 2019	Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3:2019)
Biocompatibility	14	EN ISO 10993-1: 2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
	15	EN ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
	16	EN ISO 10993-10:2023	Biological evaluation of medical devices — Part 10: Tests for skin sensitization (ISO 10993-10:2021)
	17	EN ISO 10993-11: 2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
	18	ISO 10993-18:2020/A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
	19	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Performance	20	DIN61634:1993	Surgical dressings: elastic bandage for fixation