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) [DE]
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: 693666261031000RG
Trade Name: Nonsterile Gauze Balls
Name of the device: Nonsterile Gauze Balls
EMDN Code: M0201050102, Cotton Gauze Pads, Without X-Ray Detectable Thread, Non-Sterile

Intended Purpose: Intended for clean and absorb body-surface exudates near wounds, or to apply topical medication. It only contacts intact skin or medications.

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.

CS used or Standard applied: Please find in Annex II.
Identification of the device: Please find in Annex I.

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.

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2026-04-27
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.	Catalogue No.	Kinstar REF No.	Specification	Packaging Configuration
1	2616102	C003117	40‘s×40‘s, 17th, 2.5×2.5cm, square shape	1000 pcs/PE bag, 1 bag/carton
2	2612103	C003118	40‘s×40‘s, 20th, Ø3cm, round shape	500 pcs/PE bag, 1 bag/carton
3	2612202		40‘s×40‘s, 20th, Ø3cm, round shape	500 pcs/PE bag, 6 bag/carton
4	2613103	C003119	40‘s×40‘s, 20th, Ø4cm, round shape	500 pcs/PE bag, 1 bag/carton
5	2613203		40‘s×40‘s, 20th, Ø4cm, round shape	500 pcs/PE bag, 6 bag/carton
6	2614102	C003120	40‘s×40‘s, 20th, Ø7cm, round shape	250 pcs/PE bag, 1 bag/carton
7	2614202		40‘s×40‘s, 20th, Ø7cm, round shape	250 pcs/PE bag, 8 bag/carton

Annex II --- European Harmonization and International Standard list

No.	Standards	Content
1	EN ISO 13485: 2016/A11: 2021	Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	ISO 15223-1: 2021/Amd1: 2025	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements - Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific
3	EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
4	EN ISO 14971: 2019/A11: 2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5	EN 62366-1:2015/A1: 2020	Medical devices-Application of usability engineering to medical devices - Amendment 1
6	MEDDEV 2.7.1 rev 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 901385/EEC
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 - Amendment 1
8	ISTA 2A: 2011	Partial simulation performance test procedure
9	MEDDEV 2.12-1: 2013	Guidelines on a medical devices vigilance system
10	ISO/TR 20416: 2020	Medical devices - Post-market surveillance for manufacturers
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)
14	ISO 10993-1: 2025	Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
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	ISO 10993-18: 2020/A1: 2022	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
18	EN ISO 10993-23: 2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
19	REACH Regulation 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals
20	CLP Regulation 1272/2008	Classification, Labelling and Packaging of Substances and Mixtures,

		Amending and Repealing Directives 67548/EEC and 1999/45/EC, and amending Regulation (EC) No 190712006
21	EN 14079: 2003	Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze