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: 6971872201031001LC
Name of the device: Sterile Gauze Balls
EMDN Code: M0201050101, Cotton Gauze Pads, Without X-Ray Detectable Thread, Sterile
UMDNS Code: 13700, Sponges, Gauze
GMDN Code: 48134, Woven gauze pad

Intended Purpose: The Sterile Gauze Balls is an external use device intended for use to absorb fluids, cleaning skin, mucous membranes or wounds, treating and protecting wounds, typically in a surgical setting. To be placed directly on a patient's wound to absorb exudate.

Risk Class of the Device: Class I sterile, 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: Because the devices are placed on the market in sterile condition, the procedures set out in Chapters I and III of Annex IX are applied. The notified body involved to the aspects relating to establishing, securing, and maintaining sterile conditions.

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.

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

EC-Certificate No.: G11 097364 0014 Rev. 00
Certificate Valid from: 2023-02-10
Certificate Valid until: 2028-02-09

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2023-05-30
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.	Catalogue Number	Specification	Packaging Configuration
1	1386310	20x20cm, round	10pcs/pouch, 30pouches/box, 2boxes/carton
2	138633	20x20cm, round	3pcs/pouch, 50pouches/box, 4boxes/carton

2. Photograph of Sterile Gauze Balls

Photo 1 --Sterile Gauze Balls

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)
	2	EN ISO 11135:2014/A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014/Amd 1:2018)
Labeling	3	ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part1: General requirements
	4	EN ISO 20417: 2021	Medical devices- Information to be supplied by the manufacturer (ISO 20417:2021)
Risk management	5	EN ISO 14971:2019/A11:2021	Medical devices-Application of risk management to medical devices (ISO 14971:2019)
Usability	6	IEC 62366-1:2015/A1:2020	Medical devices-Application of usability engineering to medical devices
Clinical Evaluation	7	MEDDEV 2.7.1 rev 4	Guidance document for clinical evaluation
Sampling Inspection	8	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	9	ISTA 2A: 2011	Partial simulation performance test procedure
PMS	10	MEDDEV 2.12-1:2013	Guidelines on a medical devices vigilance system
PSUR	11	ISO/TR 20416: 2020	Medical devices - Post-market surveillance for manufacturers
Environment	12	EN ISO 14644-1: 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
	13	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)
	14	EN ISO 14644-3: 2019	Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3:2019)
Biocompatibility	15	EN ISO 10993-1: 2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
	16	EN ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
	17	EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008/Amd 1:2019)
	18	EN ISO 10993-10:2023	Biological evaluation of medical devices — Part 10: Tests for skin sensitization (ISO 10993-10:2021)
	19	EN ISO 10993-11: 2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
	20	ISO 10993-18:2020/A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
	21	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Sterile	22	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
	23	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO

			11607-2:2019)
	24	EN ISO 11737-1:2018/A1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1-2018/Amd 1:2021)
	25	EN ISO 11737-2: 2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
	26	EN 868-5: 2018	Packaging for terminally sterilized medical devices --- Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
	27	EN ISO 11138-1: 2017	Sterilization of health care products --- Biological indicators --- Part 1: General requirements (ISO 11138-1:2017)
	28	EN ISO 11138-2: 2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
Performance	29	EN 14079:2003	Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze