EU Declaration of Conformity

Manufacturer Name: Kingstar Medical (Xianning) Co., Ltd.
SRN of the Manufacturer: CN-MF-000006015
Manufacturer Address: No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China.
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, Hamburg D-20537, Germany
Location be established: Germany

Basic UDI-DI: 6971872201321001M8
Name of the device: Sterile Surgical Gown
EMDN Code: T020401,Standard Surgical Gowns
UMDNS Code: 11901, Gowns, Operating Room, Disposable
GMDN Code: 35091, Surgical gown, single-use

Intended Purpose: Sterile surgical gown can be worn on surgeons and nurses to prevent the dander of doctor from spreading to the open surgical wound and the body fluids of patients from transferring to medical staff, playing a role of bidirectional biological protection.

Risk Class of the Device: Class I sterile, based on Rule 1 of ANNEX VIII of Regulation (EU) 2017/745.
--All non-invasive devices are classified as class I
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: EN 13795-1: 2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
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

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2023.02.15
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	277026	Gowns sterile | SMS, blue, 130x155cm	1pcs/pouch, 50 pouches/carton
2	277046	Gowns sterile | SMS, blue, 130x150cm	1pcs/pouch, 50 pouches/carton
3	277056	Gowns sterile | SMS, blue, 125x145cm	1pcs/pouch, 50 pouches/carton

2 Photograph of Sterile Gown

Photo 1 --- Sterile Gown | SMS

Photo 2 --- Gown | SMS

Annex II --- European Harmonization and International Standard list

Category	No.	Standards	Content
QMS	1	EN ISO 13485:2016	Quality management systems — Requirements for regulatory purposes
	2	21 CFR QSR 820	Quality management system
	3	EN ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
Labeling	4	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part1:General requirements
	5	EN ISO 20417:2021	Medical devices- Information to be supplied by the manufacturer
	6	21 CFR Part 801	Labeling- Medical device
Risk management	7	ISO 14971:2019	Medical devices- Application of risk management to medical devices

Usability	8	IEC 62366-1:2015	Medical devices- Application of usability engineering to medical devices
Clinical Evaluation	9	MEDDEV 2.7.1 rev 4	Guidance document for clinical evaluation
Sampling Inspection	10	ISO 2859-1:1999	Sampling procedures for inspection by attributes--Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
Transportation	11	ISTA 2A: 2011	Partial simulation performance test procedure
PMS	12	MEDDEV 2.12-1 rev 8, January 2013	Guidelines on a medical devices vigilance system
PSUR	13	ISO/TR 20416: 2020	Medical devices - Post-market surveillance for manufacturers
Environment	14	ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
	15	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
	16	ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
Biocompatibility	17	ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	18	ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
	19	ISO 10993-7: 2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
	20	ISO 10993-10: 2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
	21	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	22	ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
Sterile	23	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
	24	ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
	25	ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
	26	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	27	BS 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

	28	ISO 11138-1:2017	Sterilization of health care products --- Biological indicators --- Part 1: General requirements
	29	ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
Performance	30	EN 13795-1: 2019	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns