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: 6971872201321000M6
Name of the device: Nonsterile Surgical Gown
EMDN Code: T020401,Standard Surgical Gowns
UMDNS Code: 11901, Gowns, Operating Room, Disposable
GMDN Code: 35091, Surgical gown, single-use

Intended Purpose: Nonsterile 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, 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: 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: 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	277326	Gowns sterilisable | SMS, blue, 130x155cm	1pcs/pouch, 50 pouches/carton
2	277346	Gowns sterilisable | SMS, blue, 130x150cm	1pcs/pouch, 50 pouches/carton
3	277356	Gowns sterilisable | SMS, blue, 125x145cm	1pcs/pouch, 50 pouches/carton

2 Photograph of Non-sterile Gown

Photo --- Non-sterile Gown | SMS (in sterile packaging)

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
Labeling	3	EN 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
	5	21 CFR Part 801	Labeling- Medical device
Risk management	6	ISO 14971:2019	Medical devices- Application of risk management to medical devices
Usability	7	IEC 62366-1:2015	Medical devices- Application of usability engineering to medical devices
Clinical Evaluation	8	MEDDEV 2.7.1 rev 4	Guidance document for clinical evaluation
Sampling	9	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			inspection
Transportation	10	ISTA 2A: 2011	Partial simulation performance test procedure
PMS	11	MEDDEV 2.12-1 rev 8, January 2013	Guidelines on a medical devices vigilance system
PSUR	12	ISO/TR 20416: 2020	Medical devices - Post-market surveillance for manufacturers
Environment	13	ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
	14	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
	15	ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
Biocompatibility	16	ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	17	ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
	18	ISO 10993-10: 2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
	19	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	20	ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
Performance	21	EN 13795-1: 2019	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns