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: 6971872201381000P8
Name of the device: Nonsterile Examination Gloves
EMDN Code: T0102, Examination/Treatment Gloves
UMDNS Code: 11882, Gloves, Examination/Treatment
GMDN Code: 56286, Nitrile examination/treatment glove, non-powdered, non-antimicrobial

Intended Purpose: Intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary or medical purposes. The device is used mainly as a two-way barrier to protect patient/staff against contaminants. It is single-use device.

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: 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

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	230356	C039001	5142410010	Nonsterile Examination Gloves	Nitrile gloves, blue; size: L/4±0.2g	4 pcs/PE bag, 250 bags/carton
2	230358	C039002	5142410020		Nitrile gloves, blue; size: XL/4.5±0.2g	4 pcs/PE bag, 250 bags/carton

2. Photograph of Nonsterile Examination Gloves

Photo 1 --- Examination Gloves

Photo 2 --- Examination Gloves in nonsterile packaging

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	EN 455-1:2020	Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
	21	EN 455-2:2015	Medical gloves for single use – Part 2: Requirements and testing for physical properties
	22	EN 455-3:2015	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
	23	EN 455-4:2015	Medical gloves for single use – Part 4: Requirements and testing for shelf life determination