

Declaration of Conformity

(Sterile products)

Manufacturer:

Name: Kingstar Medical (Xianning) Co., LTD

Address: No.79 Yong'andong Road Xian'an District 437100 Xianning City, Hubei Province,
PEOPLE'S REPUBLIC OF CHINA

Authorised Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, D-20537, Hamburg, Germany

Product Name: See Appendix 1

List of CE-labeled Products: See Appendix 1

Classification (MDD, Annex IX): See Appendix 1

UMDNS code: See Appendix 1

Conformity Assessment Route: Annex V + Annex VII

Declaration: We hereby declare that the manufacturer is exclusively responsible for the declaration of conformity, the above mentioned products meet the provisions of the following EC Council Directives (MDD 93/42/EEC) and the relevant harmonised standards used. All supporting documentations are retained under the premises of the manufacturer and the Authorised Representative. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

- **Medical Device Directive:** COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
- **Relevant Harmonised Standards Used:** See Appendix 2

Notified Body Name: TÜV SÜD Product Service GmbH

Address: Ridlerstr. 65, 80339 Munich, Germany

Identification No.: CE0123

EC-Certificate No.: G2S 097364 0012

Certificate expired date: 2024-05-26

For and on behalf of
KINGSTAR MEDICAL (XIANNING) CO., LTD.
金士达医疗(咸宁)有限公司

Signature: 

Position: President

Date: 2021-06-07

Authorized Signature(s)

Appendix 1 of Declaration of Conformity --- List of Products

Wero Item No.	Kingstar Item No.	Product Name	Description of product	Classification Rule	Classification	UMDNS code
120066	5142350071	Sterile first aid dressing series	first aid dressing, DIN 13151-K,sterile bandage 3m x 6cm, pad 6 x 8 cm on side PE coated, 750 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
120068	5142350081	Sterile first aid dressing series	first aid dressing, DIN 13151-M,sterile bandage 4m x 8cm, pad 8 x 10 cm on side PE coated, 400 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
120070	5142350091	Sterile first aid dressing series	first aid dressing, DIN 13151-G, sterile bandage 4m x 10cm, pad 10 x 12 cm on side PE coated, 360 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
130016	5142430051	Sterile surgical dressing sheet	Bandaging cloth, sterile, 60 x 80 cm, DIN 13152-B, 500 pcs / carton	Rule 4	Class Is	17604 (Wraps, Burn)
130021	5142430041	Sterile surgical dressing sheet	Bandaging cloth, sterile, 80 x 120 cm, DIN 13152-A, 250 pcs / carton	Rule 4	Class Is	17604 (Wraps, Burn)
130031	5142430061	Sterile surgical dressing sheet	Burn-dressing, non-woven both sides PE coated (40 x 60 cm), DIN 13152-BR, 500 pcs / carton	Rule 4	Class Is	17604 (Wraps, Burn)
130032	5142430071	Sterile surgical dressing sheet	Burn-dressing, non-woven both sides PE coated (60 x 80 cm), DIN 13152-A, 60 pcs / carton	Rule 4	Class Is	17604 (Wraps, Burn)
120048	5142400051	Sterile Pressure bandage	Pressure bandage, sterile, 90 pcs / carton	Rule 4	Class Is	10284(Bandages, Pressure)
71005	5142460011	Sterile eye pad	Eye compress, sterile,600 pcs / carton	Rule 4	Class Is	11661 (Eye Pads)
71067	5142130031	Sterile wound dressing	wound compress, 10 x 10cm, sterile, compress: nonwoven pad, 220 g/sqm, both sides PE coated, 1200 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
110023	5142400101	Sterile elastic bandages	quick association (finger),sterile, elastic bandage 30 x 4cm(streched), pad 4cm x 6cm, 1500 pcs / carton	Rule 4	Class Is	10274 (Bandages)

110009	5142400111	Sterile elastic bandages	Dressing (bandage-handed), sterile, elastic bandage 40 x 6cm(streched), pad 4cm x 6cm, 400 pcs / carton	Rule 4	Class Is	10274 (Bandages)
110029	5142440031	Sterile elastic bandages	head bandage, sterile, 90 pcs / carton	Rule 4	Class Is	10274 (Bandages)
140061	5142110041	Sterile First aid dressing with self-adhesive bandages	First aid dressing with self-adhesive bandages in blue, sterile, bandage 8cm x 3m, pad 8cm x 10cm, 200 pcs / carton	Rule 4	Class Is	10288 (Bandages, Self-Adherent)
71080	5142130041	Sterile Absorbent dressing	Absorbent dressing, sterile, fleece material with a filling of cellulose. Not wound adhesive, size 20cm x 40cm, 1 pc / paper-foil package, 120 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
71020	5142020011	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 5cm x 5cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box, 27 boxes/ carton	Rule 4	Class Is	13700 (Sponges, Gauze)
71021	5142020021	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 7,5cm x 7,5cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box, 16 boxes/ carton	Rule 4	Class Is	13700 (Sponges, Gauze)
71022	5142020031	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 10cm x 10cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box, 16 boxes/ carton	Rule 4	Class Is	13700 (Sponges, Gauze)
110083	5142460021	Sterile eye bandage	Werola-eye bandage, sterile, bandage: 3m stretched elastic x 6cm, 2 pcs eye pad 6cm x 8cm, 400 pcs / carton	Rule 4	Class Is	11325 (Dressings, Nonadherent)
130013	5142430031	Sterile surgical dressing sheet	Bandaging cloth, sterile, 40 x 60 cm, DIN 13152-BR, 500 pcs / carton	Rule 4	Class Is	17604 (Wraps, Burn)
71006	/	Sterile eye pad	Eye compress, sterile, 5 packs / box	Rule 4	Class Is	11661 (Eye Pads)
71007	/	Sterile eye pad	Eye compress, sterile, 50 packs / box	Rule 4	Class Is	11661 (Eye Pads)

71025	/	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 5cm x 5cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box	Rule 4	Class Is	13700 (Sponges, Gauze)
71026	/	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 7,5cm x 7,5cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box	Rule 4	Class Is	13700 (Sponges, Gauze)
71027	/	Sterile gauze sponges	sterile gauze sponges 40's x 40's, 17 threads, 10cm x 10cm- 8 layers, with folded edges, 2 pcs / pouch, 25 pouches / box	Rule 4	Class Is	13700 (Sponges, Gauze)
130014	/	Sterile surgical dressing sheet	Bandaging cloth, sterile, 40 x 60 cm, DIN 13152-BR, 20 packs / box	Rule 4	Class Is	17604 (Wraps, Burn)
110039	/	Sterile elastic bandages	Dressing (bandage-handed), sterile, elastic bandage 40 x 6cm(streched), pad 4cm x 6cm, 10 Stk/Pkg	Rule 4	Class Is	10274 (Bandages)
110040	/	Sterile elastic bandages	quick association (finger),sterile, elastic bandage 30 x 4cm(streched), pad 4cm x 6cm, 10 Stk/Pkg	Rule 4	Class Is	10274 (Bandages)
71069	/	Sterile wound dressing	wound compress, 10 x 10cm, sterile, compress: nonwoven pad, 220 g/sqm, both sides PE coated, 6 Stk/Pkg	Rule 4	Class Is	11325 (Dressings, Nonadherent)
71073	/	Sterile wound dressing	wound compress, 10 x 10cm, sterile, compress: nonwoven pad, 220 g/sqm, both sides PE coated, 100 Stk/Pkg	Rule 4	Class Is	11325 (Dressings, Nonadherent)
120067	/	Sterile first aid dressing series	first aid dressing, DIN 13151-K,sterile bandage 3m x 6cm, pad 6 x 8 cm on side PE coated, 25 Stk/Pkg	Rule 4	Class Is	11325 (Dressings, Nonadherent)

120069	/	Sterile first aid dressing series	first aid dressing, DIN 13151-M, sterile bandage 4m x 8cm, pad 8 x 10 cm on side PE coated, 20 Stk/Pkg	Rule 4	Class Is	11325 (Dressings, Nonadherent)
120071	/	Sterile first aid dressing series	first aid dressing, DIN 13151-G, sterile bandage 4m x 10cm, pad 10 x 12 cm on side PE coated, 15 Stk/Pkg	Rule 4	Class Is	11325 (Dressings, Nonadherent)

Appendix 2 of Declaration of Conformity --- European Harmonization and International Standard list

No.	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of superseded standard
1	EN 556-1: 2001 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices	31.7.2002	EN 556: 1994 + A1: 1998	30.4.2002
2	EN 556-1: 2001/AC: 2006	15.11.2006		
3	EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1: 2016, Corrected version 2017-03)	This is the first publication	EN 980:2008	31.12.2017
4	EN 1041: 2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041: 1998	31.8.2011
5	EN 1422: 2014 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	17.04.2014	EN 1422: 1998	
6	EN ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1: 2009)	2.12.2009	EN ISO 10993-1: 2009	21.3.2010
7	EN ISO 10993-1: 2009/AC: 2010	18.1.2011		
8	EN ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5: 2009)	2.12.2009	EN ISO 10993-5: 1999	31.12.2009
9	EN ISO 10993-10: 2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	23.6.2010		
10	EN ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7: 2008)	19.2.2009		
11	EN ISO 10993-7: 2008/AC: 2009	7.7.2010		
12	EN ISO 11138-2: 2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2: 2006)	2.12.2009	EN ISO 11138-2: 2006	21.3.2010
13	EN ISO 11140-1: 2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1: 2005)	2.12.2009	EN ISO 11140-1: 2005	21.3.2010
14	EN ISO 11607-1: 2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1: 2006, including Amd 1: 2014)	18.7.2017		
15	EN ISO 11607-2:2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2: 2006, including Amd 1: 2014)	18.7.2017		
16	EN ISO 11737-1: 2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1: 2006)	7.9.2006	EN 1174-1: 1996 EN 1174-2: 1996 EN 1174-3: 1996	31.10.2006
17	EN ISO 11737-1: 2006/AC: 2009	2.12.2009		
18	EN ISO 11737-2: 2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in	7.7.2010		

	the definition, validation and maintenance of a sterilization process (ISO 11737-2: 2009)			
19	EN ISO 14937: 2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937: 2009)	7.7.2010	EN ISO 14937: 2000	30.4.2010
20	EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices (ISO 14971: 2007, corrected version 2007-10-01)	30.8.2012	EN ISO 14971: 2009	30.8.2012
21	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	28.6.2014		
22	EN 62366-1: 2015 Medical devices – Part 1: Application of usability engineering to medical devices	30.06.2015		
23	EN ISO 13485: 2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)	30.8.2012	EN ISO 13485: 2003	31.8.2012
24	EN ISO 13485: 2012/AC:2012	30.8.2012		
25	MEDDEV 2.7/1 Revision 4, Clinical evaluation, a Guide for manufacturers and notified bodies, under directives 93/42/EEC and 90/385/EEC	01.7.2016		
26	DIN 13151: 2008 Surgical dressings - Dressing packs	01.12.2008		
27	DIN 13152: 2017 Surgical dressings - Surgical sheets	15.10.2017		