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: 6971872201161001MS
Registered Trade Name / Mark: Kingstar
Name of the device: Sterile First Aid Dressing
CND Code: M030402010101, Elastic Support Bandages, Non-Adhesive, Extensible In One Direction, High Extensibility
UMDNS Code: 11326, Dressing Pads
GMDN Code: 47011, First aid absorbent pad/bandage

Intended Purpose: A wound cover intended to be used as an initial, short-term treatment after injury. The pad is applied directly to the wound, and the bandage is subsequently wrapped around the pad and secured. The device is intended for use in the home or a clinical setting to protect wounds, arrest bleeding, and introduce medications placed on the pad.

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: The procedures set out in Chapters I and III of Annex IX are applied. The notified body involved.

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.
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: 2022-10-11
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.	Reference Number	Color	Specification	Packaging Configuration
1	C135005	White	KL Verbandpaeckchen 60 x 80 mm	1 Piece/ Pouch, 400 Pouches/ Box
2	C135006	White	KL Verbandpaeckchen 80x100mm	1 Piece/ Pouch, 400 Pouches/ Box
3	C135007	White	KL Verbandpaeckchen 100x120mm	1 Piece/ Pouch, 360 Pouches/ Box

2. Photograph of Sterile First Aid Dressing

Photo 1 --- Sterile First Aid Dressing in sterile packaging

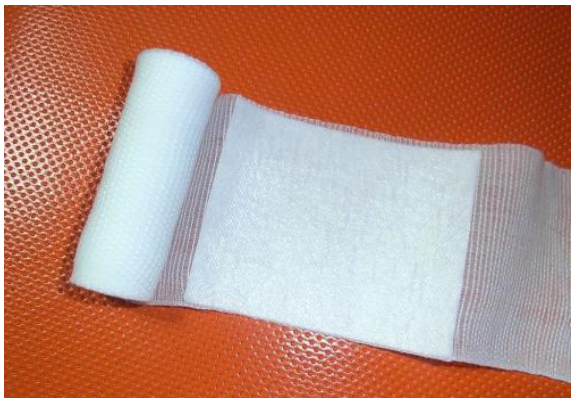

Photo 2 --- Sterile First Aid Dressing

Annex II --- 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	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+A1:2013Information supplied by the manufacturer of medical devices	25.9.2013	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	ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1	08.2018		
9	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
10	EN ISO 10993-10: 2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	21.8.2013	EN ISO 10993-10: 2010	23.6.2010
11	EN ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7: 2008)	19.2.2009		
12	EN ISO 10993-7: 2008/AC: 2009	7.7.2010		
13	EN ISO 11138-2: 2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators (ISO 11138-2: 2017)	29.3.2017	EN ISO 11138-2: 2009	21.3.2010
14	EN ISO 11140-1: 2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1: 2014)	12.11.2014	EN ISO 11140-1: 2009	21.3.2010
15	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: (ISO 11607-1: 2019)	15.01.2020	EN ISO 11607-1:2017	18.7.2017
16	ISO 11607-1: 2019 Packaging for terminally sterilized medical devices	02.2019		
17	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements (ISO 11607-2: 2019)	15.01.2020	EN ISO 11607-2:2017	18.7.2017
18	ISO 11607-2: 2019 Packaging for terminally sterilized medical devices	02.2019		
19	EN ISO 11737-1: 2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1: 2018)	31.1.2018	EN ISO 11737-1: 2006	31.10.2006
20	EN ISO 11737-2: 2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility (ISO 11737-2: 2009)	7.7.2010		
21	ISO 11737-2: 2019 Sterilization of medical devices – Microbiological methods	12.2019		
22	DIN 13151 Verbandmittel - Verbandpäckchen			
23	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
24	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
25	EN ISO 14971: 2019 Medical devices - Application of risk management	18.12.2019	ISO 14971: 2012	
26	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	20.11.2019	EN ISO 11135:2014	28.6.2014
27	EN 62366-1: 2015 Medical devices – Part 1: Application of usability engineering to medical devices	30.06.2015		
28	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	First publication	EN ISO 13485: 2012	31.3.2019
29	EN ISO 13485:2016/AC:2018	28.03.2018	ISO 13485:2016	
30	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		