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)
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: 6971872201031011LF
Name of the device: Sterile X-Ray Detectable Gauze Balls
EMDN Code: M0201050201, Cotton Gauze Pads, With X-Ray Detectable Thread, Sterile
UMDNS Code: 13705, Sponges, X-ray Detectable
GMDN Code: 38496, Radiopaque woven surgical sponge, sterile

Intended Purpose: Sterile X-Ray Detectable Gauze Balls is a device intended to be used inside the body, on a surgical incision or applied to internal organs or structures to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination during a procedure.

Risk Class of the Device: Class IIa, based on Rule 6 of ANNEX VIII of Regulation (EU) 2017/745.
All surgically invasive devices intended for short-term use are classified as class IIa.

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: 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

EC-Certificate No.: G10 097364 0013 Rev. 00
Certificate Valid from: 2023-01-30
Certificate Valid until: 2028-01-29

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: 

Heruntergeladen von Gast (IP 216.73.217.10) am 25.11.2026 um 08:16 Uhr · sana.swiss

Annex I --- Identification of the Device Covered by the EU Declaration of Conformity

1. Identification of the Device

Table --- Identification of the Device

Sterile X-Ray Detectable Gauze Balls

Classification	Meditrade Code	Meditrade Name	Kingstar name	Kingstar REF
IIa	1075	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103084X
IIa	1180	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103001X
IIa	1181	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103081X
IIa	1182	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103086X
IIa	1186	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103094X
IIa	4012	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103095X
IIa	4319	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103089X
IIa	4320	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103090X
IIa	4324	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103083X
IIa	4325	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103091X
IIa	4326	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103088X
IIa	4329	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103082X
IIa	4333	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103092X
IIa	4337	BeeSanaMulltupfer RK steril	Sterile X-ray detectable Gauze Balls	C103085X
IIa	4089	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103099X
IIa	4311	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103100X

Heruntergeladen von Gast (IP 216.73.217.10) am 25.11.2026 um 08:16 Uhr · sana.swiss

IIa	4339	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103101X
IIa	4340	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103103X
IIa	4341	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103104X
IIa	4342	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103105X
IIa	4343	BeeSanaPräpariertupfer RK steril	Sterile X-ray detectable Gauze Balls	C103102X
IIa	4004	BeeSanaSpitztupfer RK steril	Sterile X-ray detectable Gauze Balls	C103097X
IIa	4161	BeeSanaSpitztupfer RK steril	Sterile X-ray detectable Gauze Balls	C103098X

2. Photograph of Sterile X-Ray Detectable Gauze Balls



Photo 1 ---
X-Ray Detectable Gauze Balls in sterile packaging

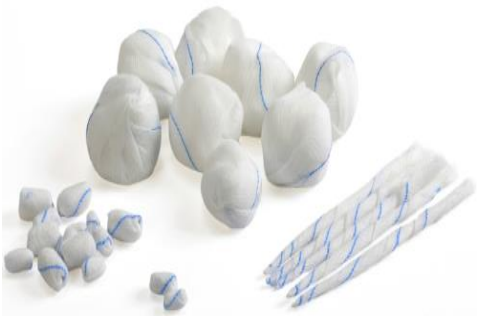


Photo 2 ---
X-Ray Detectable Gauze Balls

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
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
2	EN 556-1: 2001/AC: 2006	15.11.2006	
3	EN ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	06/07/2021	EN ISO 15223-1:2016
4	EN 1041:2008+A1:2013Information supplied by the manufacturer of medical devices	25.9.2013	EN 1041: 1998
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: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	2018-08	EN ISO 10993-1: 2009
7	EN ISO 10993-1: 2018/AC: 2010	18.1.2011	
8	ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1	08.2018	ISO 10993-1:

Heruntergeladen von Gast (IP 216.73.217.10) am 25.11.2026 um 08:16 Uhr · sana.swiss

			2009
9	EN ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	20/05/2009	EN ISO 10993-5: 1999
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
11	EN ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008-10	EN ISO 10993-7: 1995
12	ISO 10993-7:2008/Amd 1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants	2019-12	
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
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
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
16	ISO 11607-1: 2019 Packaging for terminally sterilized medical devices	02.2019	ISO 11607-1: 2016/Amd 1:2014
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	ISO 11607-2: 2019 Packaging for terminally sterilized medical devices	02.2019	ISO 11607-2: 2016/Amd 1:2014
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
20	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	2019-12	ISO 11737-2:2009
21	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
22	EN ISO 14971: 2019 Medical devices - Application of risk management to medical devices	18.12.2019	ISO 14971: 2012
23	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
24	IEC 62366-1: 2015/Amd 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices	17/06/2020	IEC 62366-1: 2007/Amd 1:2014
25	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	02/03/2016	EN ISO 13485: 2012
26	EN ISO 13485:2016/AC:2018	28.03.2018	ISO 13485:2016
27	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	MEDDEV 2.7/1 Revision 3
28	EN ISO 14644-1-2015 Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	23/12/2015	EN ISO 14644-1-1999
29	EN 14079: 2003 Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze	23/04/2003	First publication

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