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: 6971872201031010LD
Name of the device: Nonsterile X-Ray Detectable Gauze Balls
EMDN Code: M0201050202, Cotton Gauze Pads, With X-Ray Detectable Thread, Non-Sterile
UMDNS Code: 13705, Sponges, X-ray Detectable
GMDN Code: 38496, Radiopaque woven surgical sponge

Intended Purpose: Nonsterile 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 class IIa, 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:

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

1. Identification of the Device

Table --- Identification of the Device

Nonsterile X-Ray Detectable Gauze Balls

Classification	Meditrade Code	Meditrade Name	Kingstar name	Kingstar REF
IIa	1169	BeeSanaPräpariertupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003066X
IIa	1170	BeeSanaPräpariertupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003068X
IIa	1171	BeeSanaPräpariertupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003071X
IIa	1173	BeeSanaPräpariertupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003075X
IIa	4043	BeeSanaFadentupfer RK	Nonsterile X-ray detectable Gauze Balls	C003054X
IIa	1110	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003057X
IIa	1114	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003050X
IIa	1115	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003051X
IIa	1117	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003052X
IIa	1119	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003053X
IIa	1154	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003047X
IIa	1155	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003048X
IIa	1349	BeeSanaMulltupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003049X
IIa	1238	BeeSanaSpitztupfer RK unsteril	Nonsterile X-ray detectable Gauze Balls	C003062X

2. Photograph of Nonsterile X-Ray Detectable Gauze Balls

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

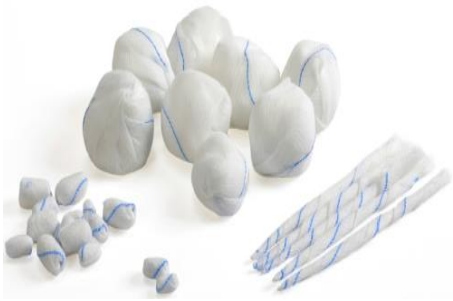

Photo 2 --- Nonsterile X-Ray Detectable Gauze Balls

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 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
2	EN 1041:2008+A1:2013Information supplied by the manufacturer of medical devices	25.9.2013	EN 1041: 1998
3	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
4	EN ISO 10993-1: 2018/AC: 2010	18.1.2011	
5	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
6	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
7	EN ISO 14971: 2019 Medical devices - Application of risk management to medical devices	18.12.2019	ISO 14971: 2012
8	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
9	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	02/03/2016	EN ISO 13485: 2012
10	EN ISO 13485:2016/AC:2018	28.03.2018	ISO 13485:2016
11	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
12	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
13	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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