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: 6971872201011010KP
Name of the device: Nonsterile X-Ray Detectable Gauze Sponges
CND Code: M0201020202, Cotton Gauzes, Folded, With X-Ray Detectable Thread, Not Sterile
UMDNS Code: 13705, Sponges, X-ray Detectable
GMDN Code: 38496, Radiopaque woven surgical sponge

Intended Purpose: Nonsterile X-Ray Detectable Gauze Sponges 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:

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 Sponges

Classification	Meditrade Code	Meditrade Name	Kingstar name	Kingstar REF
IIa	1003	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002033X
IIa	1005	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002080X
IIa	1009	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002082X
IIa	1011	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002083X
IIa	1013	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002084X
IIa	1015	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002085X
IIa	1017	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002034X
IIa	1019	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002086X
IIa	1021	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002087X
IIa	1024	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002089X
IIa	1034	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002090X
IIa	1037	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002088X
IIa	1039	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002035X
IIa	1054	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002092X
IIa	1090	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002091X
IIa	2715	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002093X
IIa	2717	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002094X
IIa	2724	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002095X
IIa	2727	BeeSanaMullkompresse RK unsteril	Nonsterile X-ray detectable Gauze Sponges	C002044X

2. Photograph of Nonsterile X-Ray Detectable Gauze Sponges

Photo 2 --- X-Ray Detectable Gauze Sponges

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