# 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:** 6971872201021011L4
**Name of the device:** Sterile X-Ray Detectable Lap Sponges
**EMDN Code:** M0201030201, Laparotomy Cotton Gauzes, With X-Ray Detectable Thread, Sterile
**UMDNS Code:** 13705, Sponges, X-ray Detectable
**GMDN Code:** 38496, Radiopaque woven surgical sponge

**Intended Purpose:** Sterile X-Ray Detectable Lap 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 transient 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: 

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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**

| Classification | Meditrade Code | Meditrade Name | Kingstar name | Kingstar REF |
|---|---|---|---|---|
| IIa | 1571 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010073X |
| IIa | 1572 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010086X |
| IIa | 1574 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010087X |
| IIa | 1587 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010088X |
| IIa | 1591 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010082X |
| IIa | 1593 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010078X |
| IIa | 1594 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010091X |
| IIa | 1595 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010081X |
| IIa | 1596 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010092X |
| IIa | 1597 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010095X |
| IIa | 1664 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010077X |
| IIa | 1665 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010089X |
| IIa | 1666 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010079X |
| IIa | 1667 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010091X |
| IIa | 1669 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010072X |
| IIa | 1677 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010080X |
| IIa | 1680 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010085X |
| IIa | 1682 | BeeSanaBauchtuck RK | Sterile X-ray detectable Lap Sponges | C1010070X |

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|---|---|---|---|---|
| | | steril | | |
| IIa | 1684 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010084X |
| IIa | 1685 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010071X |
| IIa | 4501 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010094X |
| IIa | 4504 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010093X |
| IIa | 4515 | BeeSanaBauchtuck RK steril | Sterile X-ray detectable Lap Sponges | C1010083X |

**2. Photograph of Sterile X-Ray Detectable Lap Sponges**

Drawings and photos of device:

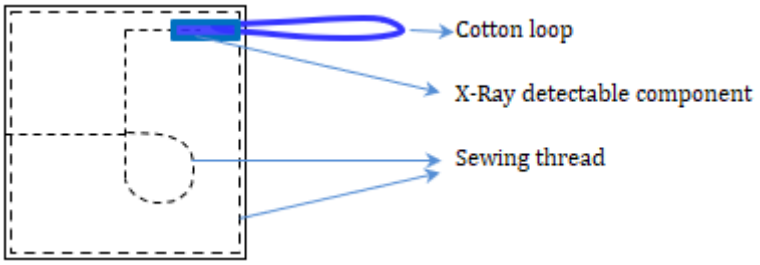




**Photo 1 ---**
**X-Ray Detectable Lap Sponges in sterile packaging**



**Photo 2 ---**
**X-Ray Detectable Lap 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 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 | |

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|---|---|---|---|
| 8 | ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1 | 08.2018 | ISO 10993-1: 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<br>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<br>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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