

| Doc. No.     | KSX/TD-GBXN-017 | Title       | EU Declaration of Conformity of Nonsterile X-Ray Detectable Gauze Balls |            |       |
|--------------|-----------------|-------------|-------------------------------------------------------------------------|------------|-------|
| Ver./Rev.No. | A/0             | Issued Date | 2023.02.15                                                              | Page/Total | 1 / 3 |

## 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 |
|----------------|----------------|------------------------------------|-----------------------------------------|--------------|
| Ila            | 1169           | BeeSanaPräpariertupfer RK unsteril | Nonsterile X-ray detectable Gauze Balls | C003066X     |
| Ila            | 1170           | BeeSanaPräpariertupfer RK unsteril | Nonsterile X-ray detectable Gauze Balls | C003068X     |
| Ila            | 1171           | BeeSanaPräpariertupfer RK unsteril | Nonsterile X-ray detectable Gauze Balls | C003071X     |
| Ila            | 1173           | BeeSanaPräpariertupfer RK unsteril | Nonsterile X-ray detectable Gauze Balls | C003075X     |
| Ila            | 4043           | BeeSanaFadentupfer RK              | Nonsterile X-ray detectable Gauze Balls | C003054X     |
| Ila            | 1110           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003057X     |
| Ila            | 1114           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003050X     |
| Ila            | 1115           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003051X     |
| Ila            | 1117           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003052X     |
| Ila            | 1119           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003053X     |
| Ila            | 1154           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003047X     |
| Ila            | 1155           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003048X     |
| Ila            | 1349           | BeeSanaMulltupfer RK unsteril      | Nonsterile X-ray detectable Gauze Balls | C003049X     |
| Ila            | 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<br>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+A1:2013 Information 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                |