# 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) [DE]
**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:** 6971872201141001M4
**Trade Name**: Sterile Tongue Depressor
**Name of the device:** Sterile Tongue Depressor
**EMDN Code:** V9001, Tongue Depressors, Single-Use
**MDR Certificate No.:** G11 097364 0014 Rev. 01

**Intended Purpose:** Intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

**Risk Class of the Device:** Class I sterile, based on Rule 5 of ANNEX VIII of Regulation (EU) 2017/745.
*-All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as class I if they are intended for transient use.*

**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:** Ridlerstraße. 65, 80339 Munich, Germany
**Identification No.:** CE0123

**Signed for and on behalf of:**
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2025.04.22
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**

| No. | REF No. | Specification | Packaging Configuration |
|---|---|---|---|
| 1 | 9665 | 150mm×18mm×1.6mm | 1 pc/blister pouch, 100 pouches/box, 10 boxes/carton |

### 2. Photograph of Sterile Tongue Depressor



**Photo 1 --- Tongue Depressor in sterile packaging**



**Photo 2 --- Tongue Depressor**

## Annex II --- European Harmonization and International Standard list

| Category | No. | Standards | Content |
|---|---|---|---|
| QMS | 1 | EN ISO 13485:2016/A11:2021 | Quality management systems — Requirements for regulatory purposes (ISO 13485:2016) |
| Labeling | 2 | ISO 15223-1:2021/Amd 1:2025 | Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirement-Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific |
| | 3 | EN ISO 20417: 2021 | Medical devices- Information to be supplied by the manufacturer (ISO 20417:2021) |
| Risk management | 4 | EN ISO 14971:2019/A11:2021 | Medical devices-Application of risk management to medical devices (ISO 14971:2019) |
| Usability | 5 | IEC 62366-1:2015/A1:2020 | Medical devices-Part 1: Application of usability engineering to medica devices-Amendment 1 |
| Clinical Evaluation | 6 | MEDDEV 2.7.1 rev 4 | Guidance document for clinical evaluation |
| Sampling Inspection | 7 | ISO 2859-1:1999/A1:2011 | Sampling procedures for inspection by attributes--Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection-Amendment 1 |
| Transportation | 8 | ISTA 2A: 2011(2012): | Partial simulation performance test procedure |
| PMS | 9 | MEDDEV 2.12-1:2013 | Guidelines on a medical devices vigilance system |
| PSUR | 10 | ISO/TR 20416: 2020 | Medical devices - Post-market surveillance for manufacturers |
| Environment | 11 | EN ISO 14644-1: 2015 | Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015) |
| | 12 | EN ISO 14644-2: 2015 | Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) |
| | 13 | EN ISO 14644-3: 2019 | Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3:2019) |

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|---|---|---|---|
| Biocompatibility | 14 | EN ISO 10993-1: 2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (IS0 10993-1: 2018, including corrected version 2018-11) |
| | 15 | EN ISO 10993-5: 2009 | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| | 16 | EN ISO 10993-7:2008/A1:2022 | Biological evaluation of medical devices -Part 7: Ethylene oxide sterilization residuals -Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019) |
| | 17 | EN ISO 10993-10:2023 | Biological evaluation of medical devices — Part 10: Tests for skin sensitization (ISO 10993-10:2021) |
| | 18 | EN ISO 10993-11: 2018 | Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2017) |
| | 19 | ISO 10993-18:2020/A1:2023 | Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials with in a risk management process AMENDMENT 1: Determination of the uncertainty factor |
| | 20 | EN ISO 10993-23:2021 | Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) |
| Sterile | 21 | 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 -Amendment 1: Revision of Annex E, Single batch release (lS0 11135:2014/Amd 1:2018) |
| | 22 | EN ISO 11607-1:2020/A1:2023 | EN ISO 11607-1:2020/A1: 2023: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems- Amendment 1: Application of risk management (ISO 11607-1:2019/Amd 1:2023) |
| | 23 | EN ISO 11607-2:2020/A1:2023 | Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes- Amendment 1: Application of risk management (ISO 11607-2:2019/Amd 1:2023) |
| | 24 | EN ISO 11737-1:2018/A1:2021 | EN ISO 11737-1:2018/A1: 2021: Sterilization of health care products-Microbiological methods -Part 1: Determination of a population of microorganisms on products-Amendment 1(ISO 11737-1-2018/Amd 1:2021) |
| | 25 | EN ISO 11737-2: 2020 | Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019) |
| | 26 | EN 868-5: 2018 | Packaging for terminally sterilized medical devices --- Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods |
| | 27 | EN ISO 11138-1: 2017 | Sterilization of health care products --- Biological indicators --- Part 1: General requirements (ISO 11138-1:2017) |

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| | 28 | EN ISO 11138-2: 2017 | Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017) |
| Substances | 29 | REACH Regulation 1907/2006 | Registration, Evaluation, Authorization and Restriction of Chemicals |
| | 30 | CLP Regulation 1272/2008 | Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67548/EEC and 1999/45/EC, and amending Regulation (EC) No 190712006 |

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