# Declaration of Conformity to Regulation(EU) 2017/745 on Medical Devices

CONTEC MEDICAL SYSTEMS CO., LTD.
No.112 Qinhuang West Street, Economic ＆Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE’S REPUBLIC OF CHINA

SRN of Manufacturer :CN-MF-000007715

EU REP

Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

SRN of Authorised Representative: DE-AR-000005129

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
We keep all supporting documentation and ensure that the authorised representative has the necessary documentation permanently available.

| | |
|---|---|
| **BASIC UDI-DI:** | 69450401KT100H5 |
| **PRODUCT AND TRADE NAME:** | Insect bite helper |
| **EMDN CODE:** | Z129099 |
| **CATALOGUE NUMBER/MODEL:** | KT100, KT101, KT102, KT103, KT104, KT120 |
| **RISK CLASS OF THE DEVICE:** | Class IIa , according to Annex VIII Rule 9 |

We,（CONTEC MEDICAL SYSTEMS CO., LTD.）herewith declare that the stated medical devices meet REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.
The harmonised standards and/or CS used and in relation to this conformity see Appendix.

| | |
|---|---|
| **NOTIFIED BODY:** | TÜV SÜD Product service GmbH<br>Ridlerstr 65, D-80339 München, Germany |
| **NOTIFIED BODY IDENTIFICATION NUMBER:** | 0123 |
| **CONFORMITY ASSESSMENT PROCEDURE:** | Regulation (EU) 2017/745, Annex IX excluding chapter II |
| **(EC) CERTIFICATE(S):** | G15 050972 0058 Rev. 01 |
| **PLACE, DATE OF ISSUE:** | Qinhuangdao, 2026/02/28 |
| **NAME AND FUNCTION, SIGNATURE:** | Hu Kun,Chairman/ manufacturer |

# Declaration of Conformity
# to Regulation(EU) 2017/745 on Medical Devices

## Appendix: list of (harmonised - EN) standards

| No. | Standards | Title and Description | Remark |
|---|---|---|---|
| 1 | EN ISO 13485:2016/ A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) | / |
| 2 | EN ISO 14971:2019/ A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) | / |
| 3 | EN 60601-1:2006/ A13:2024 | Medical electrical equipment - Part 1: General requirements for safety | / |
| 4 | EN 60601-1-2:2015/ A1:2021 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | / |
| 5 | EN 60601-1-11:2015/ A1:2021 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment | / |
| 6 | EN 60601-1-6:2010/ A2:2021 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | / |
| 7 | EN 62366-1:2015/ A1:2020 | Medical devices - Part 1: Application of usability engineering to medical devices | / |
| 8 | EN 62304:2006/ A1:2015 | Medical device software - Software life-cycle processes | / |
| 9 | EN ISO 10993-1:2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10) | / |
| 10 | EN ISO 20417:2021 | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12) | / |
| 11 | EN ISO 10993-5:2009 | Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity | / |
| 12 | EN ISO 10993-10:2023 | Biological evaluation of medical devices - Part 10: Tests for skin sensitization | / |
| 13 | EN ISO 10993-23:2021 | Biological evaluation of medical devices - Part 23: Tests for irritation | / |
| 14 | EN ISO 15223-1:2021/ A1:2025 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements - Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific (ISO 15223 1:2021/Amd 1:2025) | / |

# Declaration of Conformity
# to Regulation(EU) 2017/745 on Medical Devices

| No. | Standards | Title and Description | Remark |
|---|---|---|---|
| 15 | ISTA 3A:2018 | Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less | / |
| 16 | EN IEC 62506:2023 | Methods for product accelerated testing | / |
| 17 | EN 62471:2008 | Photobiological safety of lamps and lamp systems | The insect bite helper of model KT120 is not applicable to this standard. |
| 18 | EN ISO 17664-2:2023 | Processing of health care products - Information to beprovided by the medical device manufacturer for the processing of medical devices -Part 2:Non-critical medical devices(ISO 17664-2:2021) | / |