

# 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



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.

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**BASIC UDI-DI:** 69450401G3BC

**PRODUCT AND TRADE NAME:** Laryngoscope blades

**CATALOGUE NUMBER/MODEL:** G3, G4, C3, C4

**RISK CLASS OF THE DEVICE:** Class I according to rule 5 Annex VIII

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.

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**CONFORMITY ASSESSMENT PROCEDURE:** Regulation(EU) 2017/745, Annex II + III

**PLACE, DATE OF ISSUE:** QINHUANGDAO, 2023/08/04

**NAME AND FUNCTION, SIGNATURE:** HUKUN,Chairman/ manufacturer

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

| NO. | Reference          | Title                                                                                                                   |
|-----|--------------------|-------------------------------------------------------------------------------------------------------------------------|
| 1   | EN ISO 13485:2016  | Medical devices - Quality management systems - Requirements for regulatory purposes                                     |
| 2   | ISO 10993-1:2018   | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process              |
| 3   | ISO 10993-5:2009   | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity                                      |
| 4   | ISO 10993-10:2021  | Biological evaluation of medical devices - Part 10: Tests for skin sensitization                                        |
| 5   | ISO 10993-23:2021  | Biological evaluation of medical devices - Part 23: Tests for irritation                                                |
| 6   | IEC 62366-1:2020   | Medical devices - Part 1: Application of usability engineering to medical devices                                       |
| 7   | EN ISO 14971:2019  | Medical devices - Application of risk management to medical devices                                                     |
| 8   | EN ISO15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements |
| 9   | ISO 20417:2021     | Medical devices - Information to be supplied by the manufacturer                                                        |