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

EC 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: 69450401G2BA

PRODUCT AND TRADE NAME: Laryngoscope blades

CATALOGUE NUMBER/MODEL: G2,C2

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.

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