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: 69450401CMS-GS1JJ

PRODUCT AND TRADE NAME: Video Laryngoscope

CATALOGUE NUMBER/MODEL: CMS-GS1, CMS-GS2

RISK CLASS OF THE DEVICE: Class I according to rule 10 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

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 ON MEDICAL DEVICES

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	IEC60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	IEC60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
4	IEC60601-2-18:2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
5	IEC60601-1-6:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	IEC 62366-1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
7	IEC62304:2006+A1:2015	Medical device software - Software life-cycle processes
8	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
9	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
10	EN ISO15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
11	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer