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: 69450401IGN-IK7

PRODUCT AND TRADE NAME: CUFF

CATALOGUE NUMBER/MODEL: IGN0002, IGN0009

RISK CLASS OF THE DEVICE: Class I according to rule I 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, 2023/08/08

NAME AND FUNCTION, SIGNATURE: HUKUN,Chairman/ manufacturer

CONTEC MEDICAL SYSTEMS CO., LTD. 康泰医学系统（秦皇岛）股份有限公司

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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 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
3	ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
4	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation