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: 69450401BGNXE

PRODUCT AND TRADE NAME: ECG Cable

CATALOGUE NUMBER/MODEL: BAT0032, AAT0005

RISK CLASS OF THE DEVICE: Class I according to rule 13 Annex VIII

APPLIED STANDARDS: ANSI/AAMIEC53:2013/(R)2020
ECG trunk cables and patient leadwires

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, 2024/11/20

NAME AND FUNCTION, SIGNATURE: HUKUN,Chairman/ manufacturer