EU DECLARATION OF CONFORMITY

MANUFACTURER: **CONTEC MEDICAL SYSTEMS CO., LTD**

ADDRESS: No.112 Qinhuang West Street, Economic ＆Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

EC REP Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

PRODUCT : Urine Analyzer, BC401

CONFORMITY ASSESSMENT ROUTE: Annex II

We,（CONTEC MEDICAL SYSTEMS CO., LTD）herewith declare that the stated medical device meets the essential requirements of the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment . All supporting documentation is retained at the premises of the manufacture.
This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

STANDARD(S) APPLIED :
ETSI EN 300 328 V2.2.2 (2019-07) Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band ;Harmonised Standard for access to radio spectrum (article 3.2-Radio);
EN 62479-2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) (article 3.1 (a)-Health);
ETSI EN 301 489-1 V2.2.3 (2019-11) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;Part 1:Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility (article 3.1 (b)-EMC);
ETSI EN 301 489-17 V3.2.4 (2020-09) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;Part 17:Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility (article 3.1 (b)-EMC).

CE MARK: CE

SIGNED FOR AND ON BEHALF OF: **CONTEC MEDICAL SYSTEMS CO., LTD.**

PLACE AND DATE OF ISSUE: Qinhuangdao, CHINA Date: 2023/02/02

SIGNATURE: HUKUN,Chairman/ manufacturer