DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/746 ON IN VITRO DIAGNOSTIC 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: 69450401BC401AU

PRODUCT AND TRADE NAME: Urine analyzer

PRODUCT CODE: W020101020102

CATALOGUE NUMBER/MODEL: BC401

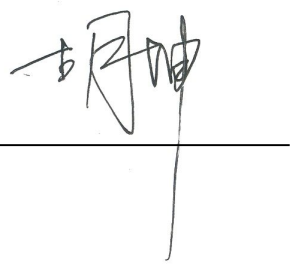
RISK CLASS OF THE DEVICE: Class A according to rule 5 Annex VIII

We, （CONTEC MEDICAL SYSTEMS CO., LTD）herewith declare that the stated vitro diagnostic medical devices meet REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices.

CONFORMITY ASSESSMENT PROCEDURE: Regulation(EU) 2017/746, Annex II + III

PLACE, DATE OF ISSUE: QINHUANGDAO, 2023/01/11

NAME AND FUNCTION, SIGNATURE: HUKUN,Chairman/ manufacturer



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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC62366-1:2020	Medical device-Part 1: Application of usability engineering to medical device
2	IEC60601-1-6:2020	Medical Electrical Equipment-Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
3	ISO 14971:2019	Medical devices-Application of risk management to medical devices
4	IEC62304:2006+AMD1:2015	Amendment 1 - Medical device software - Software life cycle processes
5	IEC 61010-1:2010/AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements; Amendment 1
6	IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
7	IEC 61326-1:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
8	IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
9	ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements
10	ISO 18113-3:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
11	EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
12	ISO15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements