DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC OF 27 OCTOBER 1998 CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.112 Qinhuang West Street, Economic ＆Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Urine Analyzer BC401
CLASSIFICATION - ANNEX Ⅱ:	General/Other
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅲ

WE, （CONTEC MEDICAL SYSTEMS CO., LTD）HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONIZED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

IDENTIFICATION NUMBER:	CE
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2015-06-18 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION: QINHUANGDAO,2015-06-18

SIGNATURE: _____ President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN 61010-1:2010 (IEC 61010-1:2010)	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements
2	EN 61010-2-101:2002 (IEC 61010-2-101:2002(Modified))	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
3	EN 61326-1:2006 (IEC61326-1:2005)	Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements
4	EN 61326-2-6:2006 (IEC 61326-2-6:2005)	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
5	EN 62304: 2006 (IEC 62304: 2006)	Medical device software - Software life-cycle processes
6	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices