Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, P. R. China
Manufacturer SRN:	CN-MF-000014156
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Automatic Urinalysis System
Model:	EU-5300Pro、EU-5600Pro
Basic UDI-DI:	69449040AB3100004ZW

Intended Purpose: Automatic Urinalysis System is an in vitro diagnosis device used for quantitative tests on human urine in laboratory environment. Clinically, the analyzer identifies and analyzes the formed elements in human urine, including red blood cell, white blood cell, White blood cell clump, bacteria, yeast, squamous epithelial cell, non-squamous epithelial cell, crystal, hyaline cast, unclassified cast, mucous strands, sperm, coccus, rod, mono-hydrate calcium oxalate crystal, di-hydrate calcium oxalate, uric acid and triple phosphate crystal.

The system can also used for semi-quantitative or qualitative testing of human urine with urinalysis test strips. It is suitable for routine clinical urine examination. The test items include: leukocyte, nitrite, urobilinogen, protein, potential of hydrogen, blood, specific gravity, ketone, bilirubin, glucose, Vitamin C, microalbumin, creatinine, calcium, color and turbidity.

Classification:	Class B (According to Rule 6 of IVDR annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	35918

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	V13 044751 0348
Start of CE-Marking:	2023-9-6

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen, 2025.11.26
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation Department

Declaration of Conformity V 2.0

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Applied Standards List

Product: Automatic Urinalysis System

Model: EU-5300Pro、EU-5600Pro

Standards Applied:

EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)
EN ISO 18113-3:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)
ISO 15223-1:2021/A1：2025	Medical devices-Symbols tobe used with information to besupplied by the manufacturerPart 1:General requirements AMENDMENT 1: Addition of definedterm for authorized representativeand modified EC REP symbol to not becountry or region specific
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
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
EN IEC 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61326-1:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro

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	diagnostic (IVD) medical equipment
IEC 62304:2015	Medical device software- Software life cycle processes
IEC 62366-1：2015	Medical devices — Application of usability engineering to medical devices
EN IEC 63000：2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

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