Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Digitally signed by Poiata Vitalie
Date: 2024.07.30 16:55:48 EEST
Reason: MoldSign Signature
Location: Moldova
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Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

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Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	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
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices