Declaration of Conformity CE

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-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-760[B], BC-760[R], BC-780[R]**

Classification: The device not in IVDD annex II and not for self testing/performance evaluation

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

GMDN: 35476

We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Start of CE-Marking: **2022-3-30**

Place, Date of Issue: **2022-3-30**

Signature: .....

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Deputy Director, Technical Regulation Department

Applied Standards List

Product:	Auto Hematology Analyzer BC-760[B], BC-760[R], BC-780[R]

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Graphical symbols for use in the labelling of medical devices
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
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro 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