

Declaration of Conformity



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-20s**
Including reagents as following:
M-30D DILUENT
M-30CFL 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: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: 

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

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EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: **Auto Hematology Analyzer**

Model: **BC-30s**
Including reagents as following:
M-30D DILUENT
M-30CFL 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)

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Declaration of Conformity V 1.0

Applied Standards List

Product: Auto Hematology Analyzer

BC-20s, BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

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| 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 18113-2:2011 | In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use |
| EN ISO 18113-3:2011 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) 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 |
| IEC 61010-2-010: 2005 | Safety requirements for electrical equipment for measurement, control and |

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| | 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 62304:2006 | 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 |
| EN ISO13485:2012 | Medical devices - Quality management systems - Requirements for regulatory purposes |