Declaration of Conformity V 11.0

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-5100**

Including reagents as following:

M-53LEO(I) LYSE
M-53LEO(II) LYSE
M-53LH LYSE
M-53D DILUENT
M-53 CLEANSER
M-53P PROBE CLEANSER

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

Digitally signed by Efre
Date: 2020.04.08 13:49:
Reason: MoldSign Signa
Location: Moldova

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: 2008-09-05

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: .....

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 11.0

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-5300**
Including reagents as following:
M-53LEO(I) LYSE
M-53LEO(II) LYSE
M-53LH LYSE
M-53D DILUENT
M-53 CLEANSER
M-53P 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: 2008-09-05

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: .....

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 11.0

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: **ULTIMA 5**

Including reagents as following:

M-53LEO(I) LYSE
M-53LEO(II) LYSE
M-53LH LYSE
M-53D DILUENT
M-53 CLEANSER
M-53P 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: 2011-08-19

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: .....

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 11.0

Applied Standards List

Product:

Auto Hematology Analyzer
BC-5100、BC-5300、ULTIMA 5
Including reagents as following:
M-53LEO(I) LYSE
M-53LEO(II) LYSE
M-53LH LYSE
M-53D DILUENT
M-53 CLEANSER
M-53P PROBE CLEANSER

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 18113-2:2011	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
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
EN 13640: 2002	Stability testing of in vitro diagnostic reagents
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
EN ISO 14971:2007	Medical devices - Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipmentfor measurement, control, and laboratory use Part 1: General requirement
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 heating of materials
EN 61010-2-081:2002 ++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 61326-1;2006	Electrical equipment for measurement control and laboratory use-EMC requirements-Part1: General requirement
EN 61326-2-6:2006	Electrical equipment for measurement control and laboratory use-EMC requirements-Part2-6: Particular requirement-In vitro diagnostic (IVD) medical equipment
EN 62366:2008	Medical devices —Application of usability engineering to medical devices
EN 62304 :2008	Medical device software- Software life cycle processes
ISO13485:2003/AC:2009	Medical devices - Quality management systems - Requirements for regulatory purposes