Declaration of Conformity V 1.0

Declaration of Conformity

CE

Manufacturer:	Beijing Mindray Medical Instrument Co., Ltd. 1F,2F,4F&5F, Building 3, No. 18 Science Park Road, Life Science Park, Changping District, Beijing 102206, China
Manufacturer SRN:	CN-MF-000022542
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Coagulation Analyzer**
Modle:	**C3100**
Basic UDI-DI:	**697080106A0320F05ETH**
Classification:	Class A (According to Rule 5 of IVDR annex VIII)
Conformity Assessment Route:	Annex II and III of IVDR
GMDN code:	56689

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:	/
Notified Body No. :	/
Identification of the Certificate:	/
Start of CE-Marking:	**2022-02-15**

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Management Representative of Beijing Mindray Medical Instrument Co., Ltd., Effective immediately.

Place, Date of Issue:	Beijing,
Signature:	2022.06.02
Name of Authorized Signatory:	Mr. Ge Pengfei
Position Held in Company:	Management Representative

Digitally signed by Poiata Vitalie
Date: 2024.07.30 16:56:40 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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Applied Standards List

Product: Auto Coagulation Analyzer

Catalogue Number: C3100

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
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 18113-3:2009)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
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 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

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EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
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

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Manufacturer: Beijing Mindray Medical Instrument Co., Ltd.
1F,2F,4F&5F, Building 3, No. 18 Science Park Road, Life Science Park, Changping District, Beijing 102206, China

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

Product: Auto Coagulation Analyzer

Model: C3100

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU, amended by Directive 2015/863/EU. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:
EN IEC 63000：2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Start of CE-Marking: 2022-02-15

Place, Date of Issue: Beijing.

Signature: 2022.06.02

Name of Authorized Signatory: Mr. Ge Pengfei

Position Held in Company: Management Representative