



Declaration of Conformity

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:

Name of Authorized Signatory: Mr. Ge Pengfei

Position Held in Company: Management Representative

Declaration of Conformity V 1.0

Applied Standards List

Product: Auto Coagulation Analyzer

Catalogue Number: C3100

Standards Applied:

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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 (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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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.

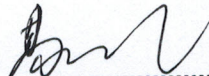
Standards Applied:

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