

Declaration of Conformity V1.0

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial
Park, Nanshan, 518057, Shenzhen, P. R. China

Manufacturer SRN: CN-MF-000014156

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

Product: Chemistry Analyzer

Model: Yumizen C230, Yumizen C240

Basic UDI-DI: 69449040SHYQ-BA24*****ML

Intended Purpose: The system is an automated chemistry analyzer for in vitro
diagnostic use in clinical laboratories and designed for in vitro
quantitative determination of clinical chemistries in serum,
plasma, urine or cerebrospinal fluid samples (sample type is
chemistry dependent).

Classification: Class A (According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 56676

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: /

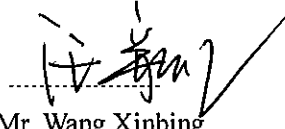
Start of CE-Marking: 2022.12.23

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:

Shenzhen, 2022.12.23

Signature:



Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: Chemistry Analyzer

Model: Yumizen C230, Yumizen C240

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 15223-1:2021	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
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
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

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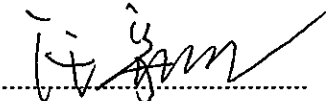
We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU, amended by Directive (EU) 2015/863. All supporting documentations are retained under the premises of the manufacturer.

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: 2022.12.23

Place, Date of Issue: Shenzhen. 2022.12.23

Signature: 

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Deputy Director, Technical Regulation Department