Declaration of Conformity CE

Manufacturer:	Hunan Mindray Medical Technology Co., Ltd. 3/F, West, Building C, Luvalley Science & Technology Innovation and Entrepreneurship Park, No.1698, Yuelu West Avenue, High-tech Development Zone, Changsha,410221,P.R.China
Manufacturer SRN:	**CN-MF-000022479**
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Automated Blood Culture Systems
Model:	TDR-X060\TDR-X120\TDR-X120II\TDR-X240\TDR-X360
Basic UDI-DI:	69380109002914T
Classification:	ClassA (According to Rule 5 of IVDR annex VIII)
Conformity Assessment Route:	IVDR Annex II+III

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:	/
Start of CE-Marking:	2022-4-24

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Hunan Mindray Medical Technology Co., Ltd., Effective immediately.

Place, Date of Issue:	Chang Sha,2022-4-24
Signature:	
Name of Authorized Signatory:	Mr. Chen Jun
Position Held in Company:	Manager, Technical Regulation

HUNAN MINDRAY MEDICAL TECHNOLOGY CO.,LTD. 迈瑞医疗科技有限公司 4301990054614

Digitally signed by Poiata Vitalie
Date: 2025.03.07 11:27:32 EET
Reason: MoldSign Signature
Location: Moldova
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Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Automated Blood Culture Systems

Model: TDR-X060\TDR-X120\TDR-X120II\TDR-X240\TDR-X360

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
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 15223-1:2016	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
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 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
EN 61010-2-101:2017	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 ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	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

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 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
EN 61010-2-101:2017	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
ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
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