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**
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Culture Bottle
Model:	TDR Resin Aerobic, TDR Resin Peds, TDR Resin Anaerobic
Basic UDI-DI:	TDR Resin Aerobic:69380109017175F TDR Resin Peds:69380109017004W TDR Resin Anaerobic: 69380109017245C
Classification:	Class A (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. 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 430199005461

Digitally signed by Poiata Vitalie
Date: 2024.10.11 13:57:15 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Applied Standards List

Product: Culture Bottle

Model: TDR Resin Aerobic, TDR Resin Peds, TDR Resin Anaerobic

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 2: In vitro diagnostic reagents 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 ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
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