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:	M-53LH LYSE
Catalogue Number:	/
Basic UDI-DI:	69449040XQSJ-003BM-5S**VC

Intended Purpose: M-53LH LYSE breaks down red blood cell membrane and converts hemoglobin to a hemoglobin complex to determine the HGB. It 2-differentiates WBCs to BASo and other WBCs, and determines WBCs amount.

Classification:	Class A (According to Rule 5（a） of IVDR annex VIII)
Conformity Assessment Route:	Annex II and III of IVDR
GMDN code:	55854

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.

Digitally signed by Stoianova Elena
Date: 2026.02.25 11:17:56 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

References to CS:	/
Notified Body:	/
Notified Body No. :	/
Identification of the Certificate:	/
Start of CE-Marking:	2022-4-19

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 Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen, 2022-4-19
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation Department

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

Applied Standards List

Product: M-53LH LYSE

Catalogue Number: /

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 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
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 (EN ISO 14971:2019)
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 (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices