Declaration of Conformity V2.0

Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	CN-MF-000014156
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Endoscope Light Source
Model:	HB500R, HB500R-TEC
Basic UDI-DI:	69449040AB065100088F
Classification:	IIa (According to Rule 10 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
EMDN code	Z120204
GMDN code:	35158
Supplementary information	/

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 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:	/
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
EC Certificate No.:	G10 044751 0176
Start of CE-Marking:	**2023-6-29**

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, 2024-4-10

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

Digitally signed by Poiata Vitalie
Date: 2026.07.24 18:06:16 EEST
Reason: MoldSign Signature
Location: Moldova

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Attachment of Declaration of Conformity: Applied Standards List-V2.0

Applied Standards List

Product: Endoscope Light Source

Model: HB500R, HB500R-TEC-

Standards Applied:

EN ISO 14971:2012/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
EN 60601-2-18: 2015	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 62471:2008	Photobiological safety of lamps and lamp systems.
EN 60825-1:2014/A11:2021	Safety of laser products – Part 1: Equipment classification and requirements.

Digitally signed by Prodan Sveatoslav
Date: 2025.04.01 13:07:50 EEST
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