DoC-MDR-2025-002(V3.0)

CE

Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu, P.R.China

Manufacturer SRN: CN-MF-000019806

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name	Models
LED Surgical Light	HyLED X9, HyLED X5, HyLED X9/X5, HyLED X5/X5, HyLED X9/X9, HyLED X9/X9/X9, HyLED X9/X9/X5, HyLED X9/X5/X5, HyLED X9M, HyLED X90, HyLED X50, HyLED X90/X50, HyLED X50/X50, HyLED X90/X90, HyLED X90/X90/X90, HyLED X90/X90/X50, HyLED X90/X50/X50, HyLED X90M, HyLED 8600, HyLED 8600/8600, HyLED 8600/8600/8600, HyLED 8600M, HyLED 760, HyLED 730, HyLED 760/760, HyLED 760/730, HyLED 730/730, HyLED 760/760/760, HyLED 760/760/730, HyLED 760/730/730, HyLED 730/730/730, HyLED 760M, HyLED 730M, HyLED 600, HyLED 600/600, HyLED 600M, HyLED C8, HyLED C7, HyLED C5, HyLED C5/C5, HyLED C7/C5, HyLED C8/C5, HyLED C7/C7, HyLED C8/C7, HyLED C8/C8, HyLED C5/C5/C5, HyLED C7/C5/C5, HyLED C8/C5/C5, HyLED C7/C7/C5, HyLED C8/C8/C5, HyLED C7/C7/C7, HyLED C8/C7/C7, HyLED C8/C8/C7, HyLED C8/C8/C8, HyLED C80, HyLED C70, HyLED C50, HyLED C50/C50, HyLED C70/C50, HyLED C80/C50, HyLED C70/C70, HyLED C80/C70, HyLED C80/C80, HyLED C50/C50/C50, HyLED C70/C50/C50, HyLED C80/C50/C50, HyLED C70/C70/C50, HyLED C80/C80/C50, HyLED C70/C70/C70, HyLED C80/C70/C70, HyLED C80/C80/C70, HyLED C80/C80/C80, HyLED C8M, HyLED C7M, HyLED C5M, HyLED Q6, HyLED Q60, HyLED Q6/Q6, HyLED Q60/Q60, HyLED Q6W, HyLED Q60W, HyLED Q6M, HyLED Q60M
LED Examination Light	HyLED 200, HyLED 200M, HyLED Q2, HyLED Q2W, HyLED Q1W, HyLED Q2M, HyLED Q1M

Basic UDI-DI: 69483505HyLEDX9Series**TS
CND code: Z120107
Classification: I (According to Rule 13 of MDR Annex VIII)
Conformity Assessment Route: Article 52.7

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.

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This declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Place, Date of Issue: Nanjing, 2025.06.23

Signature: Zhai Pei

Name of Authorized Signatory: Mr. Zhai Pei

Position Held in Company: Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List

Applied Standards List

Standard Applied:

EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/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 disturbances - Requirements and tests
EN IEC 60601-2-41:2021	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
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 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN 62304: 2006/A1:2015	Medical device software - Software life-cycle processes