DoC-MDR-2022-002(V2.0)

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
LED Examination Light	HyLED 200; HyLED 200M

Basic UDI-DI: 69483505HyLEDX9Series**TS

CND code: Z120107

Classification: I (According to Rule 13 of MDR Annex VIII)

Conformity Assessment Route: Article 52.7

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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.

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, 2022.11.23

Signature: Zhai Pei

Name of Authorized Signatory: Mr. Zhai Pei

Position Held in Company: Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2025.08.14 13:32:09 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

Applied Standards List

Standard Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	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/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-2-41: 2009+ A11:2011+ A1:2015	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
EN 60601-1-6: 2010/A1: 2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 62304: 2006/A1:2015	Medical device software - Software life-cycle processes