Declaration of Conformity V2.0

Declaration of Conformity

CE 1639

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:	4K 3D Video Endoscope
Model:	M 31030A, M 31000A, M 31030PA, M 31000PA, G 31030A, G 31000A, G 31030PA, G 31000PA
Basic UDI-DI:	69449040AB065100068B
Classification:	IIa (According to Rule 7 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
EMDN code:	Z120290
Intended Purpose:	The video endoscope is used together with the camera control unit for diagnostic and/or surgical procedures when endoscopic video support is required and is intended for short-term use.

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:	SGS Belgium NV
Notified Body No. :	1639
Identification of the Certificate:	CN23/00003444
Start of CE-Marking:	**2024-10-21**

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, 2024-10-21
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 18:05:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANA

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

Applied Standards List

Product: 4K 3D Video Endoscope

Model: M 31030A, M 31000A, M 31030PA, M 31000PA, G 31030A, G 31000A, G 31030PA, G 31000PA

Standards Applied:

ISO 8600-1:2015	Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements (ISO 8600-1:2015)
ISO 8600-3:2019	Endoscopes - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics (ISO 8600-3:2019)
ISO 8600-4:2023	Endoscopes - Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion (ISO 8600-4:2023)
ISO 8600-5:2020	Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 5: Determination of optical resolution of rigid endoscopes with optics (ISO 8600-5:2020)
ISO 8600-7:2012	Endoscopes - Medical endoscopes and endotherapy devices - Part 7: Basic requirements for medical endoscopes of wate r- resistant type (ISO 8600-7:2012)
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
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 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	Processing of health care products - Information to be provided by the Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)

EN 60601-2-18:2015	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN ISO 14971:2019/A11:2021	EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2020)
ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 17665-1:2006	Sterilization of health-care products -Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation (ISO10993-23:2021)
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/A1:2019)
ISO 13485: 2016	Medical devices-Quality management systems-Requirements for regulatory purposes
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes