Declaration of Conformity V1.0

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:	Fluid Management System
Model:	HP100G, HP200G, HP200L, HP200D
Basic UDI-DI:	69449040AB0651000589
Classification:	IIa (According to Rule 12 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
EMDN code:	Z120190
Intended Purpose:	The product is intended for irrigation and/or suction during endoscopic examination and surgery.
Supplementary information:	Included are following reusable irrigation tubing set: IR100R, following reusable suction tubing set: SU100R and following Two-Pedal Footswitch-Fluid Management System: FS200.

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:	/
Start of CE-Marking:	2023-9-13

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 2023.9.13
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

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

Applied Standards List

Product: Fluid Management System

Model: HP100G, HP200G, HP200L, HP200D

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
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/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 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
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
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)