Declaration of Conformity V1.0

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:	Diagnostic Ultrasound System
Model:	MX6、MX6S、MX6T、MX6 Exp、MX6 Pro、MX6 Super、MX6P、MX6Q、MX6W、MXG、Emerus MX6、Emerus MX6S、Emerus MX6 Exp、Anesus MX6、Anesus MX6S、Anesus MX6 Exp、Crius MX6、Crius MX6S、Crius MX6 Exp、MX GA、MX GT、MX GN、MX5E、MX EA、MX EB、MX EC、MX5、MX5S、MX5T、MX5 Exp、MX5 Pro、MX5 Super、MX5P、MX5Q、MX5W、MXI、Emerus MX5、Emerus MX5S、Emerus MX5 Exp、Anesus MX5、Anesus MX5S、Anesus MX5 Exp、Crius MX5、Crius MX5S、Crius MX5 Exp、MX IT、MX IC、MX IR、MX3H、MX HA、MX HB、MX HC、MX3、MX3S、MX3T、MX3 Exp、MX3 Pro、MX3 Super、MX3P、MX3Q、MX3W、MXC、MX3 BW、MX2、MX2 BW、MX CU、MX CB、MX CR、MX2S、MX2T、MX2 Exp、MX2 Pro、MX2 Super、MX QA、MX QB、MX QC
Basic UDI-DI:	69449040AB0501004563
Classification:	IIa (According to Rule 10 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
EMDN code:	Z110401
Supplementary information:	Included are following transducers: C6-1m、C5-2m、C5-2m-e、D7-2m、D6-2m、L14-3m、L13-3m、L12-3m、L12-3m-e、L14-3Ws、L12-3Wm、L18-6m、HS14-5Lm、7LT4s、L9-3m、SP5-1m、P4-2m、P8-2m、P10-4m、P8-2Ts、V11-3m、V10-4m、V11-3Hs、CB10-4s、ELC13-4s、CW2s、CW5s、SC6-1s、C9-3Ts、mC11-3m、C5-1m、mC5-2m、V11-3m-B、V10-4m-B

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
Identification of the Certificate:	**G10 044751 0176**
Start of CE-Marking:	**2024.11.19**

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,2024.11.19
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:	Diagnostic Ultrasound System
Model:	MX6、MX6S、MX6T、MX6 Exp、MX6 Pro、MX6 Super、MX6P、MX6Q、MX6W、MXG、Emerus MX6、Emerus MX6S、Emerus MX6 Exp、Anesus MX6、Anesus MX6S、Anesus MX6 Exp、Crius MX6、Crius MX6S、Crius MX6 Exp、MX GA、MX GT、MX GN、MX5E、MX EA、MX EB、MX EC、MX5、MX5S、MX5T、MX5 Exp、MX5 Pro、MX5 Super、MX5P、MX5Q、MX5W、MXI、Emerus MX5、Emerus MX5S、Emerus MX5 Exp、Anesus MX5、Anesus MX5S、Anesus MX5 Exp、Crius MX5、Crius MX5S、Crius MX5 Exp、MX IT、MX IC、MX IR、MX3H、MX HA、MX HB、MX HC、MX3、MX3S、MX3T、MX3 Exp、MX3 Pro、MX3 Super、MX3P、MX3Q、MX3W、MXC、MX3 BW、MX2、MX2 BW、MX CU、MX CB、MX CR、MX2S、MX2T、MX2 Exp、MX2 Pro、MX2 Super、MX QA、MX QB、MX QC

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/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 60601-2-37:2008/A1:2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
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 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	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 ISO 17664-2:2023 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices