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:	Resona I8W, Resona I8, Resona I8 Pro, Resona I8 Exp, Resona I8S, Resona I8T, Resona I8 Elite, Resona I8 Plus, Resona I8 Super, Eagus I8, Eagus I8S, Resona IY, Resona IZ, Resona IQ, Resona IP, Resona I7, Resona I7 Exp, Resona I7 Pro, Resona I7S, Resona I7T, Recho I8, Recho I8 Pro, Recho I8 Exp, Recho I8 S, Recho I7, Recho I7 Pro, Recho I7 Exp, Recho I7 S, Nuewa I8W, Nuewa I8, Nuewa I8 Exp, Nuewa I8S, Nuewa I8T, Nuewa I8 Elite, Nuewa I8 Pro, Nuewa I8 Plus, Nuewa I8 Super, Imagyn I8, Imagyn I8S, Imagyn I8T, Imagyn I8 Exp, Nuewa IY, Nuewa IZ, Nuewa IM, Nuewa I7, Nuewa I7 Exp, Nuewa I7 Pro, Nuewa I7S, Nuewa I7T, Resona I8 Easi, Resona I8 Nova, Eagus I8 Easi, Crius I8 Easi, Anesus I8 Easi, Emerus I8 Easi, Resona IN, Resona IT, Resona I7 Easi, Resona I7 Nova, Nuewa I8 Easi, Nuewa I8 Nova, Nuewa IN, Nuewa IT, Nuewa I7 Easi, Nuewa I7 Nova, Recho I8 Easi, Recho I8 Nova, Recho I7 Easi, Recho I7 Nova
Basic UDI-DI:	**69449040AB050100265X**
Classification:	IIa（According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code:	Z110401
Supplementary information:	Included are following transducers: SC6-1s, C11-3s, C6-2Gs, L9-3s, L20-5s, V11-3Hs, SP5-1s, SD8-1s, CW5s, CW2s, P7-3Ts, SC8-2s, DE11-3Ws, L14-3Ws, ELC13-4s, L13-3Ns, SD8-1E, P7-3TE, SC6-1E, SP5-1E, P7-3TU, SP5-1U, L16-4Hs, P10-4s, P8-2s, SC5-1Ns, C9-3Ts, C4-1s, 7LT4s, L12-3RCs, L12-3VNs, SP5-1Ns, V11-3HBs, CB10-4s, P8-3Ts, P8-2Ts, LAP13-4Cs

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:	**2023.8.30**

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,2023.8.30
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:	**Resona I8W, Resona I8, Resona I8 Pro, Resona I8 Exp, Resona I8S, Resona I8T, Resona I8 Elite, Resona I8 Plus, Resona I8 Super, Eagus I8, Eagus I8S, Resona IY, Resona IZ, Resona IQ, Resona IP, Resona I7, Resona I7 Exp, Resona I7 Pro, Resona I7S, Resona I7T, Recho I8, Recho I8 Pro, Recho I8 Exp, Recho I8 S, Recho I7, Recho I7 Pro, Recho I7 Exp, Recho I7 S, Nuewa I8W, Nuewa I8, Nuewa I8 Exp, Nuewa I8S, Nuewa I8T, Nuewa I8 Elite, Nuewa I8 Pro, Nuewa I8 Plus, Nuewa I8 Super, Imagyn I8, Imagyn I8S, Imagyn I8T, Imagyn I8 Exp, Nuewa IY, Nuewa IZ, Nuewa IM, Nuewa I7, Nuewa I7 Exp, Nuewa I7 Pro, Nuewa I7S, Nuewa I7T, Resona I8 Easi, Resona I8 Nova, Eagus I8 Easi, Crius I8 Easi, Anesus I8 Easi, Emerus I8 Easi, Resona IN, Resona IT, Resona I7 Easi, Resona I7 Nova, Nuewa I8 Easi, Nuewa I8 Nova, Nuewa IN, Nuewa IT, Nuewa I7 Easi, Nuewa I7 Nova, Recho I8 Easi, Recho I8 Nova, Recho I7 Easi, Recho I7 Nova**

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN60601-1:2006/ A1:2013	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/A1:2015	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 ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015	Medical devices -- 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 17664-2:2021	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
EN 60601-2-18: 2015	Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment