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
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Diagnostic Ultrasound System
Model:	Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9
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 and following needle-guided brackets: NGB-011, NGB-018, NGB-022, NGB-024, NGB-025, NGB-029, NGB-034, NGB-039, NGB-047, NGB-051, NGB-053， NGB-054
Classification:	IIa （According to Rule 10 of MDD Annex IX）
Conformity Assessment Route:	MDD Annex Ⅱ excluding(4)
GMDN code:	40761

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Start of CE-Marking:	
Place, Date of Issue:	Shenzhen 2025.12.21
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2025.10.08 18:02:40 EEST
Reason: MoldSign Signature
Location: Moldova
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Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product:	**Diagnostic Ultrasound System**
Model:	**Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9**

Standards Applied:

EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	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
EN60601-1-2:2015	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/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 10993-1:2009/AC:2010	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 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
EN 60601-2-18: 2015	Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment