Declaration of Conformity V1.0

CE 0123

Declaration of Conformity

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:	/
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Diagnostic Ultrasound System
Model:	Consona N9, Consona N9 Pro, Consona N9 Super, Consona N9P, Consona Nova, Consona N9S, Consona N9T, Consona NI, Consona NT, Consona NF, Consona NX, Consona N9K, Consona N9Q, Consona N9V, Nuewa N9, Nuewa N9 Pro, Nuewa N9 Exp, Nuewa N9 Elite, Recho N9, Recho N9 Pro, Recho N9 Exp, Recho N9 Elite, Consona N9 Exp, Consona N9 Elite, Consona N9 Ultra, Consona N9 Plus, Resona N9, Resona N9 Pro, Resona N9 Exp, Resona N9 Elite
Basic UDI-DI:	69449040AB050100305N
Classification:	IIa (According to Rule 10 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code:	Z110401
Supplementary Intended purpose:	It is intended for clinical ultrasound diagnosis and examination
information:	Included are following transducers: C5-1, SC5-1N, C6-2, 3C5A, C11-3, C6-1, L13-3N, L13-3, 7L4B, L9-3, L14-3W, 7LT4, L20-5s, L16-4Hs, SP5-1N, P4-2, P8-2, P10-4, V11-3H, V11-3HB, V11-3, V11-3B, V10-4, V10-4B,6CV1, ELC10-4, 6LE7, DE11-3, SD8-1, D7-2, D6-2B, CW5s, CW2s, P7-3Ts, P8-2Ts, P8-3Ts

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:	/
Start of CE-Marking:	**2021-12-24**

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen, 2024.12.24
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

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

Applied Standards List

Product:	**Diagnostic Ultrasound System**
Model:	Consona N9, Consona N9 Pro, Consona N9 Super, Consona N9P, Consona Nova, Consona N9S, Consona N9T, Consona NI, Consona NT, Consona NF, Consona NX, Consona N9K, Consona N9Q, Consona N9V, Nuewa N9, Nuewa N9 Pro, Nuewa N9 Exp, Nuewa N9 Elite, Recho N9, Recho N9 Pro, Recho N9 Exp, Recho N9 Elite, Consona N9 Exp, Consona N9 Elite, Consona N9 Ultra, Consona N9 Plus, Resona N9, Resona N9 Pro, Resona N9 Exp, Resona N9 Elite

Standards Applied:

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 20417:2008/A1:2013	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
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 10993-1:2020	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 17664:2017	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 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment