



## 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:** CN-MF-000014156

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg, Germany

**Product:** Diagnostic Ultrasound System

**Model:** Consona N5/ Consona N5 Pro/ Consona N5 Super/ Consona N5P/ Consona  
N5 Exp/ Consona ER/ Consona N5S/ Consona N5T/ Consona EI/ Consona  
ET/ Consona EF/ Consona EX/ Consona N5K/ Consona N5Q/ Consona  
N5V/ Consona N5 Elite/Consona N5 Ultra/ Consona N5 Plus/ Consona N3/  
Consona N3 Pro/ Consona N3 Exp

**Basic UDI-DI:** 69449040AB0501004665

**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/C5-1m/C5-2m/C5-2me/  
mC11-3m/mC5-2m/D7-2m/D6-2m/L14-3m/L13-3m/L12-3m/L12-3me/  
L12-3Wm/L18-6m/HS14-5Lm/L9-3m/SP5-1m/P4-2m/P8-2m/P10-4m/  
V11-3m/V10-4m/V11-3m-B/V10-4m-B/CW5s/CW2s

**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

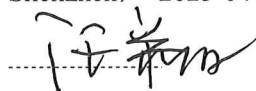
**Identification of the Certificate:** G10 044751 0176

**Start of CE-Marking:** 2025-04-02

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, 2025-04-02

**Signature:**



**Name of Authorized Signatory:** Mr. Wang Xinbing

**Position Held in Company:** Deputy Director, Technical Regulation

## Applied Standards List

**Product:**

**Diagnostic Ultrasound System**

Consona N5/ Consona N5 Pro/ Consona N5 Super/ Consona N5P/

Consona N5 Exp/ Consona ER/ Consona N5S/ Consona N5T/

**Model:**

Consona EI/ Consona ET/ Consona EF/ Consona EX/ Consona N5K/

Consona N5Q/ Consona N5V/ Consona N5 Elite/Consona N5 Ultra/

Consona N5 Plus/ Consona N3/ Consona N3 Pro/ Consona N3 Exp

### Standards Applied:

**EN ISO**

Medical devices – Application of risk management to medical

**14971:2019/A11:2021**

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 medical device labels,  
labelling and information to be supplied – Part1: General  
requirements (ISO 15223-1:2021)

**EN 60601-**

Medical electrical equipment - Part 1: General requirements for

**1:2006/A2:2021**

basic safety and essential performance

**EN 60601-1-**

Medical electrical equipment - Part 1-2: General requirements for

**2:2015/A1:2021**

basic safety and essential performance - Collateral standard:

Electromagnetic compatibility - Requirements and tests

**EN 60601-1-**

Medical electrical equipment - Part 1-6: General Requirements for

**6:2010/A2:2021**

basic safety and essential performance -Collateral standard:

usability

**EN 60601-2-**

Medical electrical equipment -- Part 2-37: Particular requirements

**37:2008/A1:2015**

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 (ISO 10993-1:2018, including corrected version 2018-10)

**EN 62304:2006/A1:2015**

Medical device software - Software life-cycle processes

**EN 62366-**

Medical devices - Part 1: Application of usability engineering to

**1:2015/A1:2020**

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