

## 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:** Digital Ultrasonic Diagnostic Imaging System

**Model:** DP-50/DP-50T/DP-50 PT/DP-50Pro/DP-50Expert/DP-50S/DP-50W/DP-70/DP-70T/DP-70 Pro/DP-70 Expert/DP-70C

**Basic UDI-DI:** 69449040AB050100145Q

**Classification:** Ila (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: 35C50EA、65C15EA、65EC10EA、75L38EA、75L53EA、10L24EA、65EB10EA、35C20EA、65EC10ED、65EL60EA、75LT38EA、D6-2EA

**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.

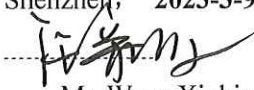
**Notified Body No. :** 0123

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

**Start of CE-Marking:** 2011-03-15

**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, 2023-3-9

**Signature:** 

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

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

## Applied Standards List

**Product:** Digital Ultrasonic Diagnostic Imaging System

**Model:** DP-50/DP-50T/DP-50PT/DP-50Pro/DP-50Expert/DP-50S/DP-50W/DP-70/DP-70T/DP-70 Pro/DP-70 Expert/DP-70C

### Standards Applied:

<b>EN ISO 14971:2019/A11:2021</b>	Medical devices – Application of risk management to medical devices
<b>EN ISO 20417 :2021</b>	Information supplied by the manufacturer of medical devices
<b>EN ISO 15223-1:2021</b>	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
<b>EN ISO 10993-1:2020</b>	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
<b>EN60601-1:2006/A1:2013</b>	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
<b>EN60601-1-2:2015</b>	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
<b>EN 60601-1-6: 2010/A1:2015</b>	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
<b>EN 60601-2-37:2008/A1:2015</b>	Medical electrical equipment -- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
<b>EN 62304:2006/A1:2015</b>	Medical device software - Software life-cycle processes
<b>EN 62366-1:2015</b>	Medical devices -- Application of usability engineering to medical devices
<b>EN ISO 17664-1:2021</b>	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
<b>ISO 17664-2:2021</b>	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