

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

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

Product: Digital Ultrasonic Diagnostic Imaging System

Model: DP-20/DP-20T/DP-21/DP-25/DP-28

Supplementary information: Included are following transducers: 35C50EB, 65EC10EB, 75L38EB, 65C15EA, 35C20EA, 75L53EA and following needle-guided brackets: NGB-004, NGB-005, NGB-007, NGB-001, NGB-002, NGB-003.

Classification: IIa (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

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: 2012-02-21

Place, Date of Issue: Shenzhen , 2018.12.29

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: Diagnostic Ultrasound System

Model: DP-20/DP-20T/DP-21/DP-25/DP-28

Standards Applied:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016	Symbols for use in the labeling of medical devices
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 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
EN60601-2-37:2008/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 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices