Declaration of Conformity V11.0

Declaration of Conformity

CE 0123

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-50,DP-50T, DP-50 PT, DP-50S, DP-50Pro, DP-50Expert
Supplementary information:	Included are following transducers: 35C50EA, 65C15EA, 65EC10EA, 65EB10EA, 75L38EA, 75L53EA, 10L24EA, 35C20EA, 65EC10ED, 75LT38EA, 65EL60EA, D6-2EA and following needle-guided brackets: NGB-001, NGB-002, NGB-003, NGB-004, NGB-005, NGB-007, NGB-009, NGB-010, NGB-016
Classification:	IIa （According to Rule 10 of MDD Annex IX）
Conformity Assessment Route:	MDD Annex II excluding(4)

GMDN code: 40761

We declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility 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:	2011-03-15
Place, Date of Issue:	Shenzhen, 2019-7-9
Signature:	.....
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V11.0

Applied Standards List

Product: Digital Ultrasonic Diagnostic Imaging System

Model: DP-50, DP-50T, DP-50 PT, DP-50S, DP-50Pro, DP-50Expert

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	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements
EN 60601-1:2006/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
EN60601-1-6:2010/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 safety 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 (ISO 17664:2017)