Declaration of Conformity V1.0

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:

Diagnostic Ultrasound System

Model:

DC-70/DC-70T/ DC-70 Pro /DC-70 Exp/DC-70S

Supplementary information:

Included are following transducers: C5-2E, C11-3E, C7-3E,

L12-3E, L14-6NE, L14-6WE, V11-3E, V11-3WE, V11-3BE, P4-2E, P7-3E, D6-2E, DE10-3E, CW5s and following needle-guided brackets: NGB-004, NGB-007, NGB-011, NGB-015, NGB-018, NGB-019, NGB-020, NGB-021,

TY-JD-02

Classification:

IIa (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

We herewith declare 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: 2014 - 8 - 22

Place, Date of Issue:

Shenzhen, 2014-8-22

Signature:

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company:

Manager, Technical Regulation Department

Applied Standards List

Product: Diagnostic Ultrasound System

Model: DC-70/DC-70T/ DC-70 Pro /DC-70 Exp/DC-70S

Standards Applied:

EN ISO 14971:2012 Medical devices - Application of risk management to

medical devices

EN 1041: 2008 Information supplied by the manufacturer with medical

devices

EN ISO 15223-1: 2012 Medical devices-Symbols to be used with medical device

labels, labeling and information to be supplied-Part 1:

General Requirements

EN 60601-1: 2006/AC:2010 Medical Electrical Equipment - Part 1: General

Requirements for Safety

EN 60601-1-2: Medical Electrical Equipment – Part 1-2: General

2007/AC:2010 Requirements for Safety -: Collateral Standard:

Electromagnetic compatibility - Requirements and tests

EN 60601-1-6: 2010 Medical electrical equipment - Part 1-6: General

Requirements for basic safety and essential performance

-collateral standard: usability

EN 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular

requirements for the safety of ultrasonic medical diagnostic

and monitoring equipment

EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation

2009+AC:2010 and testing within a risk management process

EN 62366:2008 Medical devices -- Application of usability engineering to

medical devices

EN 62304:2006 /AC:2008 Medical device software -- Software life cycle processes

EN ISO 17664:2004 Sterilization of medical devices —Information to be provided by

the manufacturer for the processing of resterilizable medical

devices.