

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

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

Product: Diagnostic Ultrasound System

Model: TE Air

Basic UDI-DI: 69449040AB050100325S

Classification: IIa (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: i3P, i3PA, z3P, z3Ps, z3Pt, e3P, e3Ps, e3Pt, a3Px, i5M, z5M, z5Ms, z5Mt, e5M, e5Ms, e5Mt, a5Mx

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: 2022-4-29

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, 2024-3-15

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

Applied Standards List

Product: Diagnostic Ultrasound System

Model: TE Air

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A2:2021	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 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
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/A1:2020	Medical devices -- Application of usability engineering to medical devices
ISO 17664-2:2021	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