Declaration of Conformity V2.0

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
Manufacturer SRN:	CN-MF-000014156
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Ventilator (Including Accessories)
Model:	TV50/TV55/TV50S
Basic UDI-DI:	69449040AB0200002743
Classification:	IIb (According to Rule 12 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code	Z120301
Intended purpose:	The ventilator is intended for providing ventilation assistance and breathing support for patients.

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 GmbHRidlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	G10 044751 0176
Start of CE-Marking:	**2022.11.18**

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, 2024.5.20
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

Applied Standards List

Product:	**Ventilator**
Model:	**TV50/TV55/TV50S**

Applied Standards:

EN ISO 14971:2019/A11:2021	Medical devices -- Application of risk management to medical devices
IEC 62304:2006+A1:2015	Medical device software - Software lifecycle processes
IEC 60601-1:2005+A1:2012 +A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8:2006+A1:2012 +A2:2020	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-12:2015+A1:2020/ IEC 60601-1-12:2014 +AMD1:2020	Medical electrical equipment -Part 1-12: General requirements for basic safety and essential performance -Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
ISO 80601-2-12 :2020	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-55:2018 /ISO 80601-2-55:2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-84:2020	Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment
ISO 80601-2-90:2021	Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
EN 1789:2020	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2014+A1:2020	Medical vehicles and their equipment-Air ambulances-Part 1: Requirements for medical devices used in air ambulances
IEC 60601-1-6:2010+A1:2013 +A2:2020	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
ISO 20417-2021	Medical devices — Information to be supplied by the manufacturer

EN ISO 5359:2014+A1:2017/ ISO 5359:2014+A1:2017	Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases
EN ISO 5356-1:2015 /ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 18082:2014+A1:2017 /ISO 18082:2014+A1:2017	Anaesthetic and respiratory equipment - Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases
EN ISO15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 4: Tests for leachables in condensate

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EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Ventilator (Including Accessories)
Model:	TV50/TV55/TV50S

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU, amended by Directive 2015/863/EU. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

EN IEC 63000：2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Start of CE-Marking: **2022.11.18**

Place, Date of Issue: Shenzhen, 2024.5.20

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation