Declaration of Conformity V5.0

Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. MindrayBuilding, 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) Eiffestralie 80, 20537 Hamburg, Germany
Product:	SpO2 Sensor
Model:	5201、520N、520A、520Ps 513A，512E、512F、512FLHs 512FLLN 512G，512H，512K，518B、518BLH、518BLL， 518C、512R，512RSx 512ES、512HS
Basic UDI-DI:	69449040AB010000413C
Classification:	lib （According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX
GMDN code:	37808
Intended purpose:	The SpO2 Sensor is intended for connecting with Mindray medical devices that support SpO2 measurements for measuring the arterial oxygen saturation and pulse rate of 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 GmbH Ridlerstrafie 65 80339 Munchen, Germany.
Notified Body No.:	0123
Identification of the Certificate:	G10 044751 0176 Rev.04
Start of CE-Marking:	2011-06-01

I hereby am appointed as the authorized person to deal with all the registration and quality management affairsin my capacity as Deputy Director of Technical Regulation of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effectiveimmediately.

Place, Date of Issue:	Shenzhen,2024.11.26
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V5.0

Applied Standards List

Product:	SpO2 Sensor
Model:	520I、520N、520A、520P、513A、512E、512F、512FLH、512FLL、512G、512H、512K、518B、518BLH、518BLL、518C、512R、512RS、512HS、512ES

Standards Applied:

EN ISO 14971:2019 A11:2021	Medical devices - Application of risk management to medical devices
ISO 20417-2021	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 60601-1:2006+A1: 2013+A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential
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 ISO 80601-2-61:2019	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC62366-1: 2015	Medical devices – Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing
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