Masimo
52 Discovery
Irvine CA 92618

EU DECLARATION OF CONFORMITY

Manufacturer:	Masimo Corporation 52 Discovery Irvine CA, 92618 USA SRN: US-MF-000010641
EU Authorized Representative:	MDSS GmbH Schiffgraben 41, 30175 Hannover Germany SRN: DE-AR-000005430
Product(s):	MightySat Rx 084399700000Z1T2A17V002HJ *(see Table 1 for details)*
GMDN/UMDNS Code(s) and terms:	45607, Pulse Oximeter
Classification:	Class IIb as per Annex VIII, Rule 10

We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the referenced product(s) in this declaration meet the provisions of:

- European Regulation (EU) No. 2017/745 (MDR), as amended
- European Directive 2014/53/EU on radio equipment (RED), as amended
- European Directive 2011/65/EU on the restriction of hazardous substances (RoHS), as amended

Harmonized Standard(s):	Refer to Table 2, List of Harmonized Standards Applied
Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-164 22 Kista Sweden CE 2862
Conformity Assessment Procedure:	Annex IX (Chapters I and III)
EU Certificate(s) issued:	28620149254
Place of Issue:	Irvine, CA
Date of Issue:	September 2, 2025
Signature:	Linus Park Vice President, Regulatory Masimo Corporation

Translated versions of this Declaration of Conformity can be provided upon request.

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TABLE 1 – List of products covered by this EU Declaration of Conformity

Product Category	Product	Trade Name	Part Number	Intended Purpose	GMDN	UMDNS	EMDN	Basic UDI-DI
Pulse Oximeter	MightySat	MightySat Rx	95162	The MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and respiration rate from the pleth (RRp). The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.	45607	17148	Z1203020408	084399700000Z1T2A17V002HJ
		MightySat Rx	95166		45607	17148	Z1203020408	084399700000Z1T2A17V002HJ

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TABLE 2 – List of Harmonized Standards Applied

Standard /CS/ Guideline	Version/Year	Title
EN ISO 13485	2016+A11:2021	Medical Devices - Quality Management Systems – Requirements for regulatory for regulatory purposes (ISO 13485:2016)
EN ISO 14971	2019+A11:2021	Medical Devices – Application of Risk Management to medical devices (ISO 14971:2019)
EN ISO 80601-2-61	2019	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017)
EN 60601-1	2006+A2:2021	Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005+A2:2020)
EN 60601-1-2	2015+A1:2021	Medical electrical equipment -- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility (IEC 60601-1-2:2014+A1:2020)
EN 60601-1-11	2015+A1:2021	Medical electrical equipment - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015+AMD1:2020)
EN 62366-1	2015+A1:2020	Medical devices – Application of usability engineering (IEC 62366-1:2015+A1:2020)
EN 60601-1-6	2010+A2:2021	2013 Medical Electrical Equipment Part 1-6: General requirements for safety - Collateral Standard: Usability (IEC 60601-1-6:2010+A2:2020)
EN 62304	2006+A1:2015	Medical device software – Software life-cycle processes (IEC 62304:2006+A1:2015)
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices – Part 1: Evaluation & Testing within a Risk Management Process (ISO 10993-1:2018)
EN ISO 10993-5	2009	Biological Evaluation of Medical Devices – Part 5: Cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-10	2023	Biological Evaluation of Medical Devices – Part 10: Tests for skin sensitization. (ISO 10993-10:2021)
EN ISO 10993-23	2021	Biological Evaluation of Medical Devices – Part 10: Tests for irritation (ISO 10993-23:2021)
EN ISO 14155	2020	Clinical Investigation of Medical Devices of Human Subjects (ISO 14155:2020)
EN ISO 20417	2021	Medical Devices – Information to be Supplied by the Manufacturer (ISO 20417:2021)
ISO 15223-1	2021	Graphical Symbols for Labeling of Medical Devices (ISO 15223-1:2021)
ISTA 2A	2011	Pre-Shipment Test