



Masimo
52 Discovery
Irvine CA 92618

EC DECLARATION OF CONFORMITY

Manufacturer's Name: Masimo Corporation

Business Address: 52 Discovery, Irvine, CA 92618, USA

European Representative: Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

Products: Masimo Instruments and Systems:

- Pulse Oximeters
- Respiratory Monitors
- EEG Monitors
- Regional Oximeters
- Physiologic Monitoring Systems
- Capnography Monitoring Systems

(see Attachment)

Classification: Class IIb (per MDD Annex IX, Rule 10)

Conformity Assessment Route: MDD Annex II (excluding section 4)

UMDNS Code(s) and Term(s): (see Attachment)

GMDN Code(s) and Term(s): (see Attachment)

Standards Applied: Refer to Essential Requirements Checklist of the Technical File or TFA-1186, Harmonized Standards Applied in support of MDD and RoHS


We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of European Directive 93/42/EEC on Medical Devices (MDD), as amended, as well as of European Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS). All supporting documentation is retained at the premises of the manufacturer.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2016.

Notified Body: TÜV SUD Product Services GmbH
Ridlerstrasse 65, 80339 Munchen-Germany
Identification no. 0123

EC-Certificate: G1 092076 0024 Rev. 00

Signature:


Linus Park
VP, Regulatory
Masimo Corporation

5/26/21
Date



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ATTACHMENT

This Declaration of Conformity applies to all of the part numbers listed in TFA-1001 for each product described in the table below.

Product Category (per EC Cert)	Product Type	Product Name	UMDNS Code and Term	GMDN Code and Term
Pulse Oximeters & Respiratory Monitors*	Masimo SET Pulse Oximeter	Radical	17148, Oximeter, Pulse	17148, Pulse Oximeter, Line Powered;
		Rad-8	17148, Oximeter, Pulse	45607, Pulse Oximeter, Battery-powered
		Rad-5, Rad-5v	17148, Oximeter, Pulse	45607, Pulse Oximeter, Battery-powered
		iSpO2 Rx	17148, Oximeters, Pulse	45607, Pulse Oximeter, Battery Powered
		MightySat ¹ , MightySat Rx ¹	17148, Oximeters, Pulse	45607, Pulse Oximeter, Battery Powered
		Masimo Personal/ Professional Health App (iOS or Android)	26752, Software, Physiologic Measurement	59378, Single-Patient Physiologic Monitoring System Application Software
		Rad-G	17148, Oximeters, Pulse	45607, Pulse Oximeter, Battery Powered
		Rad-G with Temperature	17148, Oximeters, Pulse 17888, Thermometers. Electronic. Infrared, Skin	45607, Pulse Oximeter, Battery Powered 17888, Infrared thermometer, skin
	Rainbow SET Pulse CO-Oximeter	Rad-57	17148, Oximeter, Pulse	46201, CO-Oximeter, Pulse
		Pronto		
		Pronto-7	17148, Oximeter, Pulse (primary); 17667, Oximeter, Pulse, Telemetric (secondary)	46201, CO-Oximeter, Pulse (primary); 37353, Telemetry Transmitter, Oximeter, Pulse (secondary)
		Rad-67		
		Rad-97* ²	17148, Oximeter, Pulse (primary); *12662, Monitors, Bedside, Respiration (secondary); 17667, Oximeter, Pulse, Telemetric (secondary)	46201, CO-Oximeter, Pulse (primary); *12662, Patient Monitor, Respiration (secondary); 37353, Telemetry Transmitter, Oximeter, Pulse (secondary)
		Rad-97 with NiBP* ²		
		Rad-97 with Capnography* ²		
		Rad-97 with Camera* ²		
		Rad-97 with NiBP and Camera* ²		
		Rad-97 with Capnography and Camera* ²		
		Rad-87*		
		Radical-7* ³		
		Radius-7* ⁴		
		Radius-7 Wi-Fi* ⁴		
	Docking Station	Radical Docking Station (RDS)	25207, Docking/ Charging Station,	33586, Single-patient physiologic monitoring

¹ Includes the following Masimo SET parameters: SpO2, PR, PI, PVI, RRp

² Includes the following features in addition to Masimo SET and rainbow SET parameters: RRp, ATA, InVivo, SpfO2, ORI Concordance, Eve, RPVi

³ Includes the following features in addition to Masimo SET and rainbow SET parameters: RRp, ATA, InVivo, SpfO2, ORI, Eve, RPVi

⁴ Includes the following features in addition to Masimo SET and rainbow SET parameters: RRp, ATA, InVivo



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			Physiologic Monitor (primary); 17667, Oximeter, Pulse, Telemetric (secondary)	system (primary); 37353, Telemetry Transmitter, Oximeter, Pulse (secondary)
	External Modules	External Satshare Module	20781, Physiologic Monitor Modules, Pulse Oximetry	36554, Patient Monitoring System Module, Pulse Oximetry



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Product Category (per EC Cert)	Product Type	Product Name	UMDNS Code and Term	GMDN Code and Term
	Pulse Oximetry Module	External rainbow SET Module	20781, Physiologic Monitor Modules, Pulse Oximetry	36554, Patient Monitoring System Module, Pulse Oximetry
		Rainbow SET Module		
		High Performance/ Low power Module		
		Intellivue Module		
		Rainbow SET Intellivue Module		
		uSpO2 Pulse Oximetry cables		
		uSpO2 Pulse Oximetry cable with ODU Medi-Snap		
		Vuelink Module for Philips		
		Masimo SET SpO2 Cables		
		Masimo uSpO2 for GE ApexPro		
		Masimo uSpO2 For Philips		
		rainbow SET Pulse CO-Oximetry Cables, GE Carescape SpO2		
		rainbow SET Pulse CO-Oximetry Cables, GE Carescape SpO2, Masimo		
Gas Analyzer	Gas Analyzer	NomoLine ISA CO2	12662, Monitors, Bedside, Respiration	12662, Patient Monitor, Respiration
EEG Monitors	Brain Sedation Monitoring System	SedLine Module (V1 & Next Gen)	12602, Monitors, Bedside, Electroencephalography	37323, Patient Monitoring System Module, Electroencephalographic
Regional Oximeters	Regional Oximeter	O3 Module (adult & pediatric use) O3, Philips	17942, Oximeter, Cerebral	17942, Cerebral Oximeter
Physiologic Monitoring Systems	Multi-parameter Patient Monitoring System	Root	12636, Monitoring System, Physiologic (primary); 13987, Physiologic Monitoring System, Telemetric (secondary)	33586, Single-patient physiologic monitoring system (primary); 37353, Telemetry Transmitter, Oximeter, Pulse (secondary)
		Root with NIBP and Body Temperature (aka Root Vital Signs)		