



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

Product: Masimo Accessories: (see Attachment)

- Cables: Patient/Adapter/Extension;
- EEG Sensor/Patient Cable;
- Sensor Accessories: Wraps/Clips/Covers/Pads/Bands;
- Instrument Accessories: Brackets/Cables/Power Cord/Testers/Tools

Classification: Class I (per MDD Annex IX; Rule 1)

Conformity Assessment Route: MDD Annex VII

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

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 under 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: Not applicable

(EC) Certificate: Not applicable

Signature

Linus Park
VP, Regulatory
Masimo Corporation

2/11/2021

Date



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ATTACHMENT

This Declaration of Conformity applies to all of the part numbers listed in TFA-1269 for each product described in the table below.

Type	Product Name	UMDNS Code	GMDN Code
Rainbow cables:	<u>Patient cables:</u> RC-1; RC-4; RC-12; M20-01; M20-04; M20-12; <u>Adapter Cables:</u> RC25-4RA; RC25-4; RC25-12RA; RC25-12; <u>Extension Cable:</u> RC-Ext	16312; Cable/lead	47487; Medical Device Electrical Cable, General-Purpose
RAM cables:	Dual Channel Acoustic Monitoring Cable; Acoustic Respiration Patient Cable, RC25-10, RC-10, LNC-10, Red 25 LNC-10 <u>Dual Channel Patient Cable:</u> LNC M20-10; <u>Dual Channel Rainbow Patient Cable:</u> M20-10		
LNCS cables:	<u>Patient cables:</u> LNC-1; LNC-4; LNC-10; LNC-14; LNC MP4; LNC MP10; LNC-10-P8; LNC-4-GE; LNC-10-GE; LNC-SL-10; LNC-04-DB9; LNC-10-DB9; LNC-14-DB9; LNCv-4; LNCv-10; LNC-10-NK <u>Adapter Cables:</u> LNCS to PC; LNC CMS; LNC MAC-GE; LNC MAC-SL; LNC MAC-SL2; LNC MAC-180; LNC MAC-395; LNC MAC-4 P8; LNC MAC-10 P8; <u>Extension Cable:</u> LNC-4 Ext; <u>Red patient cables:</u> RED LNC-01; RED LNC-04; RED LNC-10; RED LNC-14; RED LNCv-4; RED LNCv-10; RED 25 LNC-4; RED 25 LNC-10; RED LNC M20-01; RED LNC M20-04; RED LNC M20-10; RED LNC M20-14		
M-LNCS cables:	<u>Patient cables:</u> M-LNC-1; M-LNC-4; M-LNC-10; M-LNC-14; M-LNC MP4; M-LNC-MP10; M-LNC-10 P8; M-LNC-4-GE; M-LNC-10-GE; M-LNC-SL-10; M-LNC-04-DB9; M-LNC-10-DB9; M-LNC-14-DB9; M-LNCv-4; M-LNCv-10; M-LNC-10-NK <u>Adapter Cables:</u> M-LNC-MAC-SL2; M-LNC-MAC-SL; M-LNC-MAC-180; M-LNC-MAC-395; M-LNC-MAC P8; M-LNC-MAC-GE; M-LNC-MAC-CMS; M-LNCS to LNC; M-LNCS to PC; M-LNCS to LNC-MAC; <u>Red patient cables:</u> Red M-LNCv-4; Red M-LNCv-10 <u>EMS Cables:</u> rainbow RC-1 EMS, rainbow RC-4 EMS, rainbow RC25-1 EMS, rainbow RC25-4 EMS, rainbow RC25-1RA EMS, rainbow RC25-4RA EMS		
LNOP cables:	<u>Patient cables:</u> PC04; PC08; PC12; PC-4-GE; PC-8-GE; PC-12-GE; PC04-EXT; PC-04-DB9; PC-08-DB9; PC-12-DB9; PC-SL-12; PC1.6M; MP12; PC-12-NK		



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Type	Product Name	UMDNS Code	GMDN Code
	<u>Adapter cables:</u> MAC P8; CMS; MAC-1; MNC-1, 4'; MNC-1, 10'; MNC-1; Procal cable series; <u>Extension Cables:</u> PC04-Ext; PC04; PC1.6M; PC08; PC12; ; <u>Red patient cables:</u> RED PC-04; RED PC-08; RED PC-12; RED 25 PC-4; RED 25 PC-4RA; RED 25 PC-12; RED MNC,10'; RED MNC, 4'; Red 25 MNC,4'; Red 25 MNC,10'; Red 25RA MNC,4'; Red 25RA MNC,10'		
RD SET cables:	<u>Patient cables:</u> MD14-05; MD14-08; MD14-12; MD14-1.5;GE-05; GE-12; MP-05; MP-12; NK-05; NK-12; SL-12; MD20-05; MD20-1.5; MD20-12; Rad-G-1.5; Rad-G-5; Rad-G-12 <u>Adapter cables:</u> RD to PC'1.5; RD to LNC'3; RD to M-LNC'1.5; LNOP to RD'1.5; LNCS to RD'1; M-LNCS to RD'1; RD to LNC'1.5 <u>Extension Cables:</u> RD SET EXT-4		
RD rainbow SET cables:	MD20-12; MD20-08; MD20-05; MD20-1.5; R25-1.5; RA25-1.5; R25-05; RA25-05; R25-12; RA25-12; R25-08; RA25-8; M20-12; M20-05; M20-1.5 <u>RD Rainbow SET RAM Dual Cables:</u> M20-10; R25-12; MD20-12, M20-12		
Mountable extensions/adapters/flex cables:	PXC-16; PXC-30; PXC-50; PXC-UT16; PXC-UT30; PXC-UT50 14 pin to 20 pin Adapter Cable; PXC2-16; PXC2-30; PXC2-50; PXC2-UT16, PXC2-UT30, PXC2-UT50 Flex cables MP to R25 adapter cable R25 to MP adapter cable		
SatShare cables:	AT01; DO01; DO02; DO03; DO04; DO05; DO06; DO07; DS01; DS02; DS03; DS04; HP03; MQ01; MS01; NK01; NK02; OH01; OH02; PM01; SL01; SL02; SM01; MS11; SatShare Extension Cable		
SpO2.com cables:	NRC-180; NRC-395; NRC-GE; NRC-P8; NRC-P12; NRC-SL; NRC-SL2; NRC-SL-02		
OEM cables:	LNOP/LNCS/M-LNCS/RD Cables <i>- for Philips FAST SpO2 technology as implemented in IntelliVue</i>		
Iris Adapters:	Iris Adapter Family		
EEG sensor/patient cable:	SedLine sensor; RD SedLine sensor (Adult), RD SedLine Sensor (Pediatric) SedLine patient cable; RD Sedline patient cable	11440, Electrodes, Electroencephalographic; 16313, Cables/Leads, EEG	11440, Analytical Scalp Electrode, Single-Use; 47487, Medical Device Electrical Cable, General-Purpose
Sensor Accessories:	replacement tapes/wraps; clean shield/standard/foam wraps; adhesive squares/pads;	10030; Tapes, Adhesive;	16866; Basic Adhesive Tape



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Type	Product Name	UMDNS Code	GMDN Code
	armband; headband		
	clothing clips	10898; Clips	---
	cable covers; cable tether; light/ambient shield, finger gauge	---	33878; Cable/ Lead/ Sensor/ Probe Cover, Non-Sterile
Instrument Accessories:	power supply; cable adapters	23712; Power Supply, Signal Generator Adapters	45804; Electrical Mains Power Cable
	Testers; upgrader/service tool	20162; Testers, Pulse Oximetry Monitor	36866; Pulse Oximeter Tester
	brackets	12142; Racks, Instrument	36757; Patient Monitoring System Module Rack