



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(s): Masimo Sensors:

- SET (SpO2) Pulse Oximeter Sensors
- rainbow SET Pulse CO-Oximeter Sensors
- rainbow Acoustic Monitoring (RAM) Sensors
- Regional Oximeter Sensor
(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

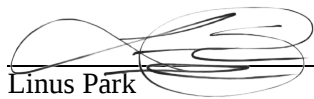
We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of European Directive 93/42/EEC on Medical Devices (MDD), as amended, as well as of European Directive 2011/65/EU on Restriction of Hazardous Substances (RoHS). 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: TÜV SUD Product Services GmbH
Ridlerstrasse 65, 80339 Munchen-Germany
Identification no. 0123

EC-Certificate: G1 092076 0021 Rev. 00

Signature:


Linus Park
VP, Regulatory
Masimo Corporation

2021-01-21
Date



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ATTACHMENT

**This Declaration of Conformity applies to all of the part numbers listed in TFA-1270
for each product described in the table below.**

Type	Product Name	UMDNS Code	GMDN Code
ReSposable sensors (SpO2):	<u>ROS:</u> Adt, Pdt <u>DOS:</u> Adt, Pdt <u>S-DOS:</u> 25, 20, 25L, 20L, 30L, 25Pt-L, 20L-500 <u>S-ROS:</u> LNCS S-ROS 3U, M-LNCS S-ROS 3U, Red S-ROS 12U, S-ROS 12U, SpaceLabs S-ROS 12U, Philips S-ROS 12U, DB9 S-ROS 12U, GE S-ROS 12U, MAC 395 S-ROS 12U, MAC 180 S-ROS 12U, MAC SL S-ROS 12U, MAC SL2 S-ROS 12U, MAC CMS S-ROS 12U, S-ROS 12-20	17594, Probes, Oximeter	31658, Probes, Pulse Oximeter, Single use; 37808, Probes, Pulse Oximeter, Reusable; 47582, Pulse CO-Oximeter probe, reusable; 47581, Pulse CO-Oximeter probe, single-use
LNCS (SpO2) sensors:	<u>Adhesive/Single Use (non-sterile):</u> Adt, Adtx, Adtx-3, Pdt, Pdtx, Pdtx-3, Inf, Inf-3, Inf-L, Neo, Neo-3, Neo-L, NeoPt, NeoPt-3, NeoPt-L, NeoPt-500, Trauma, Newborn Neonatal, Newborn Infant/Pediatrics, E1 (Ear), TFA-1 <u>Adhesive/Single Use (EO sterile):</u> Adtx-3, Pdtx-3, Inf-3, Neo-3, NeoPt-3, NeoPt-500 <u>Reusable:</u> DC-I, DC-Iv, DCI-P, DCI-Pv, DBI, TC-I, YI, Multisite-L, TF-I <u>Red:</u> LNCS TFA-1 <u>Sensor Kit:</u> Adt Adhesive & Pdtx/Inf/Neo Adhesive		
M-LNCS (SpO2) sensors:	<u>Adhesive/Single Use(non-sterile):</u> Adt, Pdt, Adtx, Adtx-3, Pdtx, Pdtx-3, Inf, Inf-3, Inf-L, Neo, Neo-3, Neo-L, NeoPt, NeoPt-3, NeoPt-L, NeoPt-500, Trauma, Newborn Neonatal, Newborn Infant/Pediatric, Blue, E1 (Ear), TFA-1 <u>Adhesive/Single Use (EO sterile):</u> Adtx-3, Pdtx-3, Inf-3, Neo-3, NeoPt-3, NeoPt-500 <u>Reusable:</u> DCI, DC-Iv, DCI-P, DCI-Pv, DBI, TC-I, YI, Multisite-L, TF-I <u>Red:</u> M-LNCS TFA-1 <u>Starter Kit:</u> M-LNCS YI		
LNOP (SpO2) sensors:	<u>Adhesive/Single Use:</u> Adt, Pdt, Inf-L, Neo-L, NeoPt-L, NeoPt, Neo, Inf, Blue, Trauma, Newborn Neonatal, Newborn Infant/Pediatric, E1 (Ear) <u>Reusable:</u> DC-I, DCI-P, TC-I, TF-I, DC-195, YI, Multisite-L, NR-125 <u>LNOPv Adhesive/Singe Use:</u> AD, PD, IN, NE		
RD (SpO2) sensors:	<u>Adhesive/Single Use:</u> Adt, Pdt, Inf, Neo, NeoPt; NeoPt-500, Trauma, Newborn Neonatal, Newborn Infant/Pediatrics, Blue, TFA-1, E1, Adt CS-2, RD SET Pdt CS-2, Inf CS-2, Neo CS-2, NeoPt CS-2, Adt CS-3, Pdt CS-3, Inf CS-3, Neo CS-3, NeoPt CS-3 <u>Training Kit:</u> Cable Sensor training kit <u>Reusable:</u> DCI, DCIP, TC-I, YI, TF-I, DBI		
Direct Connect (SpO2) Sensors:	<u>Reusable:</u> DCSC, DC-8, DC-12, DB-I-dc3, DB-I-dc8		
SpO2.com (SpO2) sensors:	<u>Adhesive/Single Use:</u> A, P, I, N, (Adt, Pdt, Neo, Inf) <u>Reusable:</u> RS-I		
Rad-G Sensor	<u>Rad-G Sensor</u>		



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Type	Product Name	UMDNS Code	GMDN Code
	<u>Rad-G YI Multisite Reusable Sensor</u>		
OEM (SpO2) Sensors:	LNOP/LNCS/M-LNCS/RD SET Sensors <i>-for Philips FAST SpO2 technology as implemented in IntelliVue</i> <i>- Nellcor compatible</i>		
Rainbow SET sensors:	<u>Adhesive/Single Use:</u> R1-25L, R1-20L, R25, R20, R25L, R20L, R1-25, R1-20 <u>ReSposable:</u> R2-25, R2-20, R2-25r, R2-20r, R2-25a, R2-20a <u>Universal ReSposable:</u> UR-ROS, UR-DOS 25, UR-DOS 20, UR-DOS 25L, UR-DOS 20L, Super UR-ROS, Super UR-DOS 25, Super UR-DOS 20, Super UR-DOS 25L, Super UR-DOS 20L <u>Reusable:</u> DCI-I, DCI-P, DCI SC-200, DCIP SC-200, DCI SC-360, DCIP SC-360, DCI SC-400, DCIP SC-400, DCI SC-1000, DCIP SC-1000, DCI-dc3, DCIP-dc3, DCI-dc8, DCIP-dc8, DCI-dc12, DCIP-dc12, DC-3 SC-200, DCP-3 SC-200, DC-3 SC-360, DCP-3 SC-360, DC-12 SC-360, DCP-12 SC-360, DC-12 SC-200, DCP-3 SC-1000, DC-3 SC-1000, DCI-6, DCIP-6, DCI-mini SC200, DCI-mini SC400, DCI-mini SC1000, Super DCI-mini SC 200, Super DCI-mini 400, Super DCI-mini 1000 <u>Red:</u> RED DCI-dc3, RED DCI-dc12, RED DCIP-dc3, RED DCIP-dc12, RED DBI-dc3, RED DBI-dc8 <u>Reusable/Direct Connect (Pronto-7):</u> 4D DC	17594, Probes, Oximeter	31658, Probes, Pulse Oximeter, Single use; 37808, Probes, Pulse Oximeter, Reusable; 47582, Pulse CO-Oximeter probe, reusable; 47581, Pulse CO-Oximeter probe, single-use
RD Rainbow SET sensors:	<u>Adhesive Single Use:</u> RD Rainbow SET-2 Adt, RD Rainbow SET-2 Pdt, RD Rainbow SET-2 Inf, RD Rainbow SET-2 Neo RD rainbow Lite SET-1 Adt, RD rainbow Lite SET-1 Pdt, RD rainbow Lite SET-1 Inf, RD rainbow Lite SET-1 Neo, RD rainbow Adt 8λ SpCO, RD rainbow Pdt 8λ SpCO, RD rainbow Inf 8λ SpCO, RD rainbow Neo 8λ SpCO <u>Reusable:</u> LNCS-II rainbow DCI 8λ SpCO, LNCS-II rainbow DCIP 8λ SpCO, LNCS-II rainbow DCI-6 8λ SpCO, LNCS-II rainbow DCIP-6 8λ SpCO, LNCS-II rainbow DCI 8λ SpHb SC 200, LNCS-II rainbow DCIP 8λ SpHb SC 200, LNCS-II rainbow DCI 8λ SpHb SC 400, LNCS-II rainbow DCIP 8λ SpHb SC 400, LNCS-II rainbow DCI 8λ SpHb SC 1000, LNCS-II rainbow DCIP 8λ SpHb SC 1000 <u>Training Kit:</u> RD rainbow Lite SET-1		
RAM sensors:	<u>Adhesive/Single Use:</u> RAS-125, RAS-125c, RAS-45, RAS-45 Inf/Neo	13754, Stethoscopes, Electronic	13754, Electronic Stethoscope
Radius PPG Tetherless Sensors:	<u>Adhesive/Single Use:</u> Radius PPG Adt, Radius PPG Neo <u>Reusable:</u> PPG Reusable Chip, Wireless Receiver M20, Wireless Receiver MD20, Wireless Receiver R25 <u>Kit:</u> Radius PPG Kit Adt, Radius PPG Kit Neo	17148, Oximeter, Pulse	46201, Co-oximeter, Pulse