



Masimo
52 Discovery
Irvine CA 92618

EU DECLARATION OF CONFORMITY

Manufacturer: Masimo Corporation
52 Discovery
Irvine, CA 92618
SRN: US-MF-000010641

EU Authorized Representative: MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
SRN: DE-AR-000005430

Product(s): RD SET Series patient cables
Basic-UDI-DI: 084399700000Z1T0B01V000EA
(see Table 1 for details)

GMDN/UMDNS Code(s) and terms: 47487; Electrical-only medical device connection cable, reusable
16312; Cable/lead

Classification: Class I (per EU MDR, Annex VIII, Rule 1)

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
- EU 2015/863: Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restrictive substances

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

Harmonized Standard(s): Refer to Table 2, List of Harmonized Standards Applied

Notified Body: N/A

Conformity Assessment Procedure: Annex II and Annex III

EU Certificate(s) issued: N/A

Place of Issue: Irvine, CA

Date of Issue: February 10, 2022

Signature:



Linus Park
VP, Regulatory

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

Product Name	Part Number	Intended Purpose	GMDN	UMDNS	Basic-UDI-DI			
RD SET MD20-1.5	4102	The RD SET Series patient cables have the same indications for use as the applicable sensors. Please see the compatible sensor’s directions for use for indications for use and prescribed information.	47487	16312	084399700000Z1T0B01V000EA			
RD SET MD20-05	4103							
RD SET MD20-12	4104							
RD SET MD14-05	4080							
RD SET MD14-08	4108							
RD SET MD14-12	4081							
RD SET GE-05	4084							
RD SET GE-12	4085							
RD SET MP-05	4082							
RD SET MP-12	4083							
RD SET NK-05	4191							
RD SET NK-12	4192							
RD SET SL-12	4087							
RD SET MD14-1.5	4675							
RD SET Rad-G-1.5	4772							
RD SET Rad-G-5	4773							
RD SET Rad-G-12	4774							
LNCS to RD Adapter Cable	4092	The RD SET Adapter Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor’s directions for use for indications for use and prescribed information.						
RD SET EXT-4	4095							
RD to M-LNC Adapter Cable	4090							
RD to PC Adapter Cable	4088							
RD to LNC Adapter Cable	4105	The RD to LNC Adapter Cable has the same indications for use as the applicable sensors. Please see the compatible sensor’s directions for use for indications for use and prescribed information.						
RD to LNC Adapter Cable	4089							

TABLE 2 – List of Harmonized Standards Applied

Standard/CS/Guideline	Version/Year	Title
EN ISO 13485	2016	Medical Devices - Quality Management Systems
EN ISO 14971	2019	Medical Devices - Application of Risk Management to Medical Devices
EN 60601-1	2006/A1:2013	Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2	2015	Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility
EN 60601-1-6	2013	Medical electrical equipment – Part 1-6: Collateral standard: Usability
EN 62366	2008	Medical devices – Application of usability engineering
EN 80601-2-61	2019	Medical electrical equipment: Particular requirements for basic safety and essential performance of pulse ox equipment
EN ISO 10993-1	2009/AC:2010	Biological Evaluation of Medical Devices – Part 1: Evaluation & test
EN ISO 10993-5	2009	Biological Evaluation of Medical Devices – Part 5: Cytotoxicity
EN ISO 10993-10	2013	Biological Evaluation of Medical Devices – Part 10: Tests for irritation & sensitization.
EN 1041	2008	Information supplied by the manufacturer
EN ISO 15223-1	2016	Graphical Symbols for Labeling of Medical Devices
EN ISO 14155-1	2011	Clinical Investigation of Medical Devices of Human Subjects
MEDDEV 2.7.1	2016	Clinical Evaluation