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 rainbow SET Series patient cables Basic-UDI-DI: 084399700000Z1T0B02V000EM *(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

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

Product Name	Part Number	Intended Purpose	GMDN	UMDNS	Basic-UDI-DI
RD rainbow SET M20-05	4256	The RD rainbow SET Series patient cables are designed to be used with the RD SET and RD rainbow SET Series sensors to provide connection with devices containing Masimo SET or Masimo rainbow SET technology Version 7.1 or higher. The patient cables are provided in a variety of lengths to support differing clinical workflows where shorter or longer distances from the monitoring device may be required.	47487	16312	084399700000Z1T0B02V000EM
RD rainbow SET M20-1.5	4255				
RD rainbow SET M20-12	4257				
RD SET MD20 - 05	4072				
RD SET MD20 - 1.5	4071				
RD SET MD20 - 12	4073				
RD SET MD20-08	4109				
RD rainbow SET R25-05	4076				
RD rainbow SET R25-08	4106				
RD rainbow SET R25-1.5	4074				
RD rainbow SET R25-12	4078				
RD rainbow SET RA25-05	4077				
RD rainbow SET RA25-08	4107				
RD rainbow SET RA25-1.5	4075				
RD rainbow SET RA25-12	4079				
RD rainbow SET MD20-1.5, EMS	4791				
RD rainbow SET MD20-04, EMS	4792				
RD rainbow SET MD20-12 EMS	4793				
RD rainbow SET R25-1.5, EMS	4794				
RD rainbow SET R25-04, EMS	4795				
RD rainbow SET R25-12	4796				
RD rainbow SET RA25-1.5, EMS	4797				
RD rainbow SET RA25-04	4798				
RD rainbow SET RA25-12, EMS	4799				

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
RoHS	2015	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