



Masimo
52 Discovery
Irvine CA 92618

EU DECLARATION OF CONFORMITY

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

EU Authorized Representative: Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover Germany
SRN: DE-AR-000005430

Product(s): M-LNCS Patient Cable Series
Basic-UDI-DI: 084399700000Z1T0B03V000EY
(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:

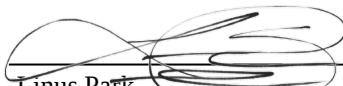

Linus Park
Vice President, Regulatory

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

Product Name	Part Number	Intended Purpose	GMDN	UMDNS	Basic-UDI-DI
rainbow RC-12	2404	The rainbow Series Patient Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor’s direction for use for indications for use and prescribed information.	47487	16312	084399700000Z1T0B03V000EY
rainbow RC-1	2405				
rainbow RC-4	2406				
M-LNC-1	2523	The M-LNC Patient 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.			
M-LNC-4	2524				
M-LNC-10	2525				
M-LNC-14	2526				
M-LNC-10-GE	2533	The M-LNC GE Patient 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.			
M-LNC-04-DB9	2534	The M-LNC DB-9 Patient 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.			
M-LNC-10-DB9	2535				



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M-LNC-14-DB9	2536	
M-LNC-4-GE	2655	The M-LNC GE Patient 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.
M-LNC-SL-10	2714	The M-LNC SL Patient 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.
M-LNC MP10	2831	The M-LNC MP Series Patient Cables and Masimo Sensors are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric, infant, and neonatal patients in hospital, hospital-type facilities, mobile, and home environments.
M-LNC MP4	3754	
RC25-12	3342	The rainbow Series Patient Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor's direction for use for indications for use and prescribed information.
RC25-12RA	3343	
RC25-4RA	3375	
Red M-LNCv-4	3513	The M-LNCv and Red M-LNCv series of 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
Red M-LNCv-10	3514	
RC25-4	3628	The rainbow Series Patient Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor's direction for use for indications for use and

		prescribed information.
RC25-1	3933	The rainbow Series Patient Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor's direction for use for indications for use and prescribed information.
RC25-1RA	3934	
M-LNC-10-NK	3985	The Masimo NK Series patient cables have the same indications for use as the applicable sensors. Please see compatible sensor's directions for use for indications for use and prescribed information.
rainbow M20-01	4236	The rainbow Series Patient Cable Series have the same indications for use as the applicable sensors. Please see the compatible sensor's direction for use for indications for use and prescribed information.
rainbow M20-04	4237	
rainbow M20-12	4238	
rainbow RC-1 EMS	4480	The rainbow Series Patient Cables, EMS 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.
rainbow RC-4 EMS	4481	
RC25-1 EMS	4482	
RC25-4 EMS	4483	
RC25-1RA EMS	4484	



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RC25-4RA EMS	4485			
RC-EXT-8	3659	The rainbow Extension Cable, RC-EXT, is designed for use with Masimo M-LNC or RC patient cables on Masimo or Masimo compatible pulse oximetry systems. When used with M-LNC patient cables, the RC-EXT is able to provide Masimo SET (SpO2 and PR) parameters. When used with RC patient cables, the RC-EXT is able to provide Masimo rainbow SET (SpO2, PR, SpCO, SpMet, SpHb) parameters.		

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 (3.1 Edition)
EN 60601-1-2	2015	Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility (4th Edition)
EN 80601-2-61	2019	Medical electrical equipment: Particular requirements for basic safety and essential performance of pulse ox equipment
EN 62366	2008	Medical devices – Application of usability engineering
EN 60601-1-6	2013	Medical electrical equipment -Part 1-6: Collateral standard: Usability
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 ISO 14155-1	2011	Clinical Investigation of Medical Devices of Human Subjects
MEDDEV 2.7.1	2016	Clinical Evaluation
EN 1041	2008	Information supplied by the manufacturer
ISO 15223-1	2016	Graphical Symbols for Labeling of Medical Devices