

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): LNCS and SpO2.com Cables
Basic-UDI-DI: 084399700000Z1T0B04V000FB
084399700000Z1T0B07V000GC
(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: September 20, 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
LNC-10	1814	The 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.	47487	16312	084399700000Z1T0B04V000FB
LNC-14	2013				
LNC-04	2017				
LNC-01	2364				
LNC-10-GE	2016	Masimo SET GE Patient Cables (LNOP Patient Cable Series and LNCS 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.			
LNC-4-GE	2430				
Red LNC-04	2055	The Red PC patient cables and the Red LNC 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 LNC-10	2056				
Red LNC-14	2057				
Red LNC M20-01	4251				
Red LNC M20-04	4252				
Red LNC M20-10	4253				
Red LNC M20-14	4254				
Red LNC-01	2365				
Red 25 LNC-10	3345				
Red 25 LNC-4RA	3376				
Red 25 LNC-4	3630				
Red 25 LNC-1	3935				
Red 25 LNC-1RA	3936				
LNC MP10, Philips	2270	The 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 hospitals, hospital-type facilities, mobile, and home environments.			
LNC MP10	2281				
MP10 Cable	3008				
LNC MP4	3755				
LNC-04-DB9	2285	The LNC DB9 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			
LNC-10-DB9	2286				

		information.			
LNC SL-10	2432	Masimo SET LNC SL-10 Patient Cables and Masimo SET LNOP PC SL-12 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.			
LNCv-4	3507	The LNCv and Red 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.			
LNCv-10	3508				
Red LNCv-4	3511				
Red LNCv-10	3512				
LNC-10-NK	3984	The Masimo NK 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.			
Red MNC Cable	2641	The Red MNC adapter 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 MNC Cable	2642				
Red 25 MNC Cable	4610				
Red 25 MNC Cable	4611				
Red 25RA MNC Cable	4612				
Red 25RA MNC Cable	4613				
MNC-I Cable	1819	The MNC-I Adapter 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.			
MNC-I Cable	2022				
LNC-4-EXT	2021	The LNCS Series Extension Cable (LNC-EXT) is designed for compatibility with either Masimo LNCS Patient Cables used with Masimo or Masimo compatible pulse oximetry systems, or with Nellcor patient cables used with Nellcor or Nellcor compatible pulse oximetry systems. The LNCS Extension Cable also provides a direct connect solution to Nellcor N180 pulse oximeters, or compatible devices utilizing Nellcor N200 pulse oximetry technology and having a DB9 connector interface at the host device.			

LNC CMS	2263	The LNCS Adapter Cables and Masimo LNCS sensors are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for adult, pediatric, infant, and neonatal patients.			
LNC MAC-GE	2264				
LNC MAC-SL	2266				
LNC MAC-SL2	2336				
		The LNCS Adapter Cables and the above LNCS sensors have been validated with Nellcor’s N-200 oximeter. The saturation accuracy of the neonatal sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.			084399700000Z1T0B07V000GC
SPO2.COM NRC-180	1810	The SPO2.COM Patient Cables are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (ApO2) and pulse rate for adult, pediatric, infant and neonatal patients.			
SPO2.COM NRC-395	1811				
SPO2.COM NRC-P12	1853				
SPO2.COM NRC-GE	1854				
SPO2.COM NRC-SL	1900	The SPO2.COM Patient Cables and the above SPO2.COM sensors have been validated with Nellcor’s N-200 oximeter. The saturation accuracy of the neonatal sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.			
SPO2.COM NRC-P8, 3M	1949				
SPO2.COM NRC-SL2	2335				

TABLE 2 – List of Harmonized Standards Applied

Standard/CS/Guide line	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	2010/ A1:2013	Medical Electrical Equipment – Part 1-6: Collateral standard: Usability
EN 62366-1	2015	Medical Devices – Application of usability engineering
EN 80601-2-61	2019	Medical Electrical Equipment: Particular requirements for basic safety and essential performance of Pulse Oximeter 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