

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Masimo Corporation

52 Discovery, Irvine, California, 92618, United States

Manufacturer SRN: US-MF-000010641

Authorised Representative Name

Medical Device Safety Service GmbH (MDSS)
Schiffgraben, 41 30175 Hannover, Germany

Scope:

Gas Monitoring Devices and Accessories
Patient Monitoring Devices and Accessories
Hemodynamic Monitoring System and Accessories

Certificate Number:

28620149254

Revision:

03

Initial Certification Date:

10 May 2023

Certificate Decision Date:

18 December 2023

Certificate Issue Date:

18 December 2023

Certificate Expiry Date:

29 April 2028



Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	CN00182-10
Audit Report Reference	CN00182-10

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620149254-00	10 May 2023	Initial Issue
28620149254-01	18 September 2023	Addition of Hemodynamic Monitoring System
28620149254-02	25 October 2023	Correction of scope



PRODUCT LIST FOR CERTIFICATE

Issued to: Masimo Corporation

Certificate number: 28620149254-03

Certificate valid from: 2023-12-18

Product list issue date:
26 January 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Patient monitoring devices and associated accessories			
Basic UDI-DI: 084399700000Y0T1B11V100DK			
4302 - Centroid	Class IIa Z12039085		2025-03-06
Basic UDI-DI: 084399700000Y1T3E00V000GC			
9095 - Patient SafetyNet System	Class IIb Z1203020292	The Patient SafetyNet (PSN) is intended to be used as a supplemental alarm system and provides real time monitoring of patient data from multiple patient monitoring devices.	2025-03-06
Basic UDI-DI: 084399700000Y1T3E00V001GE			
95097 - Patient SafetyNet Lite	Class IIb Z1203020292	The Patient SafetyNet Lite (PSN Lite) is intended to be used as a supplemental alarm system communicating with multiple patient monitoring devices. The PSN Lite provides secondary display of physiological monitoring parameters.	2026-01-26
Basic UDI-DI: 084399700000Y3T5A03V000J9			
4889 - Radius VSM NIBP Module	Class IIb Z1203020202	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospitals, healthcare facilities and home environments. The Radius VSM and accessories are intended for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVI, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of patients.	2025-03-06
Basic UDI-DI: 084399700000Z0T2A03V000EQ			

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Product	Classification and EMDN	Intended use ¹	Date Added
9036 - Radius VSM with Reusable Pod & NIBP	Class IIb Z1203020202	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospitals, healthcare facilities and home environments. The Radius VSM and accessories are intended for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVI, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of patients.	2025-03-06
Basic UDI-DI: 084399700000Z0T2A03V001E5			
9037 - Radius VSM Monitor	Class IIb Z1203020202	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospitals, healthcare facilities and home environments. The Radius VSM and accessories are intended for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVI, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of patients.	2025-03-06
Basic UDI-DI: 084399700000Z0T2A04V000F3			
9664 - Radius-7	Class IIb Z1203020202	The Radius-7 and Accessories are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), Respiratory Rate from the pleth (RRp), and/or respiratory rate (RRa).	2025-03-06
9903 - Radius-7, Wi-Fi	Class IIb Z1203020202	The Radius-7 Wearable Pulse CO-Oximeter is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).	2025-03-06
9916 - Radius-7	Class IIb Z1203020202	The Radius-7 Wearable Pulse CO-Oximeter is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).	2025-03-06
Basic UDI-DI: 084399700000Z0T2A05V000FE			
95080 - Masimo W1	Class IIb Z1203020202	Masimo W1 is intended to be worn on the wrist for the spot-checking of ECG and other continuous parameters (e.g., pulse oximetry).	2025-03-06
Basic UDI-DI: 084399700000Z0T3A00V000EA			
9515 - Root, Masimo	Class IIb Z1203020201	The Root is intended for the monitoring of multiple physiological parameters in healthcare environments. The Masimo Root Monitoring System can transmit data for supplemental remote viewing and alarming (e.g., at a central station).	2024-12-19

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z0T3A00V001EC			
9695 - Root, NIBP and Temperature	Class IIb Z1203020201	The Root NIBP and Temperature is intended for the monitoring of multiple physiological parameters in healthcare environments. The Masimo Root Monitoring System can transmit data for supplemental remote viewing and alarming (e.g., at a central station).	2025-03-06
Basic UDI-DI: 084399700000Z0T3A01V000EM			
9738 - Rad-97	Class IIb Z1203020202	The Masimo Rad-97 and Accessories are indicated for hospitals, hospital-type facilities, mobile, and home environments. The Masimo Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station). The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices	2023-05-10
9783 - Rad-97 Home Use	Class IIb Z1203020202	The Masimo Rad-97 and Accessories are indicated for hospitals, hospital-type facilities, mobile, and home environments. The Masimo Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station). The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices.	2023-05-10
9784 - Rad-97 Home Use with Camera	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp).	2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
9796 - Rad-97 with Camera	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp).	2023-05-10
Basic UDI-DI: 08439970000Z0T3A01V001EP			
95004 - Rad-97 Home Use with non-invasive blood pressure 22.9 cm x 10.2 cm x 16.5 cm (9" x 4" x 6.5") Approx. 0.91 kg. (2.0 lbs.) to 1.05 kg. (2.32 lbs.) <i>Rad-97</i>	Class IIb Z1203020202	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices. The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure. The NIBP module is designed to measure blood pressure.	2023-05-10
9785 - Rad-97 Home Use with non-invasive blood pressure, and camera	Class IIb Z1203020202	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices. The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure. The NIBP module is designed to measure blood pressure.	2023-05-10
9797 - Rad-97 with non-invasive blood pressure	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp). The optional non-invasive blood pressure (NiBP) module is intended for the noninvasive measurement of arterial blood pressure.	2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
9798 - Rad-97 with non-invasive blood pressure and camera	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp).	2023-05-10
Basic UDI-DI: 084399700000Z0T3A01V002ER			
9799 - Rad-97 with NomoLine Capnography	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp). The optional Nomoline Capnography product family is intended to be connected to other medical backboard devices for monitoring of breath rate and CO2.	2023-05-10
9802 - Rad-97 with NomoLine Capnography and Camera	Class IIb Z1203020202	The Rad-97™ Pulse CO-Oximeter® is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), Oxygen Reserve Index (ORI™) and Pleth Respiration Rate (RRp). The optional Nomoline Capnography product family is intended to be connected to other medical backboard devices for monitoring of breath rate and CO2.	2023-05-10
Basic UDI-DI: 084399700000Z0T3A19V000HS			
4898 - Masimo SafetyNet Alert	Class IIb Z1203020408	The Masimo SafetyNet Alert is intended for the continuous monitoring of physiological parameters through communication to compatible medical technologies.	2025-03-06
Basic UDI-DI: 084399700000Z0T3A20V000F4			
4736 - Masimo SafetyNet	Class IIb Z1203020408	The Masimo SafetyNet with the Radius PPG sensors are intended for the spot-checking or continuous monitoring of functional oxygen saturation (SpO2) and Pulse Rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z0T3B16V000HA			
9895 - Rad-G™ (with Temperature)	Class IIb Z1203020408	The Rad-G and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Pleth Respiration Rate (RRp). The Rad-G is intended for the noninvasive spot-checking of Temperature.	2025-03-06
Basic UDI-DI: 084399700000Z0T3B16V001HC			
9210 - Rad-G™ (with Temperature) with Sensor	Class IIb Z1203020408	The Rad-G and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR) and Pleth Respiration Rate (RRp). The Rad-G and Accessories are indicated for the noninvasive spot-checking of Temperature.	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z1T0A11V000E6			
3412 - uSpO2 Masimo SET Oximetry Cable, USB	Class IIb Z1203020408	The uSpO2 Masimo SET Oximetry Cable is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
3449 - Masimo SET uSpO2 Pulse Oximetry Cable for GE Legacy ApexPro, ApexPro CH,	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
3577 - Masimo SET uSpO2 Pulse Oximetry Cable for GE Legacy ApexPro, ApexPro CH	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
3849 - uSpO2 Cable with ODU Medi-Snap Connector, 6'	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4318 - uSpO2, Masimo SET uSpO2 Cable, Phillips	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4319 - uSpO2 Masimo SET Oximetry Cable, Masimo	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4320 - uSpO2 Masimo SET Oximetry Cable, NightOne Connector, Philips	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4321 - uSpO2 Masimo SET Oximetry Cable, NightOne Connector, Masimo	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4322 - uSpO2 Masimo SET Oximetry Cable, Dreamstation, 6', Philips	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4323 - uSpO2 Masimo SET Oximetry Cable, Dreamstation, 6', Masimo	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4730 - uSpO2 Masimo SET Oximetry Cable, USB, 6', Philips	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4775 - uSpO2 Masimo SET Oximetry Cable, E30, 6', Philips	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
5223 - uSpO2 Masimo SET Oximetry Cable, USB (Toitu)	Class IIb Z1203020408	The uSpO2 is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-06-05
Basic UDI-DI: 084399700000Z1T1B01V000EV			
4050 - RD SET DCI, SpO2, Adult Reusable Finger Clip Sensor, 3 ft	Class IIb C900301	The RD SET DCI reusable sensor is intended for the noninvasive spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4051 - RD SET DCI-P, SpO ₂ , Pediatric/Slender Digit, Reusable Finger Clip sensor 3 ft	Class IIb C900301	The RD SET DCI-P reusable sensor is intended for the noninvasive spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B01V001EX			
4052 - RD SET DBI Reusable Soft Sensor	Class IIb C900301	The RD SET DBI reusable sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B01V002EZ			
4053 - RD SET TC-I, SpO ₂ , Adult Reusable Ear Sensor, 3 ft	Class IIb C900301	The RD SET TC-I reusable sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B01V003F3			
4054 - RD SET YI, Multisite Reusable Sensor	Class IIb C900301	The RD SET YI reusable sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B01V004F5			
4055 - RD SET TF-I, Multisite Reusable Sensor	Class IIb C900301	The RD SET TF-I reusable sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B01V100F2			
4000 - RD SET Adt, SpO ₂ , PR, PI, PVI, Adult Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Adt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4001 - RD SET Pdt, SpO ₂ , PR, PI, PVI, Pediatric Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Pdt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4002 - RD SET Inf, SpO ₂ , PR, PI, PVI, Infant Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Inf sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4003 - RD SET Neo, SpO ₂ , PR, PI, PVI, Neonatal/Adult Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Neo sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4004 - RD SET NeoPt, SpO ₂ , PR, PI, PVI, Neonatal Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET NeoPt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4005 - RD SET NeoPt-500, SpO ₂ , PR, PI, PVI, Neonatal Pulse Oximeter Non-Adhesive Sensor	Class IIb C900301	The RD SET NeoPt-500 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06

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4011 - RD SET Trauma, SpO2, PR, PI, PVI, Adult Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Trauma sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4012 - RD SET Newborn Infant/Pediatric, SpO2, PR, PI, PVI, Infant/Pediatric Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Newborn Infant/ Pediatric sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4013 - RD SET Newborn Neonatal, SpO2, PR, PI, PVI, Neonatal Pulse Oximeter Adhesive Sensor	Class IIb C900301	The RD SET Newborn Neonatal sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4014 - RD SET Blue Adhesive Sensor	Class IIb C900301	The RD SET Blue sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B01V101F4			
4016 - RD SET TFA-1	Class IIb C900301	The RD SET TFA-1 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B01V102F6			
4470 - RD SET Adt CS-2 Adhesive Sensor	Class IIb C900301	The RD SET Adt CS-2 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4471 - RD SET Pdt CS-2 Adhesive Sensor	Class IIb C900301	The RD SET Pdt CS-2 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4472 - RD SET Inf CS-2 Adhesive Sensor	Class IIb C900301	The RD SET Inf CS-2 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4473 - RD SET Neo CS-2 Adhesive Sensor	Class IIb C900301	The RD SET Neo CS-2 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4474 - RD SET NeoPt CS-2 Adhesive Sensor	Class IIb C900301	The RD SET NeoPt CS-2 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4475 - RD SET Adt CS-3 Adhesive Sensor	Class IIb C900301	The RD SET Adt CS-3 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4476 - RD SET Pdt CS-3 Adhesive Sensor	Class IIb C900301	The RD SET Pdt CS-3 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4477 - RD SET Inf CS-3 Adhesive Sensor	Class IIb C900301	The RD SET Inf CS-3 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4478 - RD SET Neo CS-3 Adhesive Sensor	Class IIb C900301	The RD SET Neo CS-3 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4479 - RD SET NeoPt CS-3 Adhesive Sensor	Class IIb C900301	The RD SET NeoPt CS-3 sensor is intended for the continuous noninvasive monitoring of arterial saturation (SpO2), and pulse rate (PR).	2025-03-06
4615 - RD SET Adt CS-1 Adhesive Sensor	Class IIb C900301	The RD SET Adt CS-1 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4886 - RD SET Neo CS-1 Adhesive Sensor	Class IIb C900301	The RD SET Neo CS-1 is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B01V103F8			
4015 - RD SET E1	Class IIb C900301	The RD SET E1 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B02V000F8			
4058 - LNCS-II rainbow DCI 8λ SpHb SC 200 Reusable Sensor	Class IIb C900301	The LNCS-II rainbow DCI 8λ SpHb SC 200 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
4059 - LNCS-II rainbow DCI 8λ SpHb SC 400 Reusable Sensor	Class IIb C900301	The LNCS-II rainbow DCI 8λ SpHb SC 400 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
4060 - LNCS-II rainbow DCI 8λ SpHb SC 1000, Adult Sensor	Class IIb C900301	The LNCS-II rainbow DCI 8λ SpHb SC 1000 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
4061 - LNCS-II rainbow DCIP 8λ SpHb SC 200, Pediatric Sensor	Class IIb C900301	The LNCS-II rainbow DCIP 8λ SpHb SC 200 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
4062 - LNCS-II rainbow DCIP 8λ SpHb SC 400, Pediatric Sensor	Class IIb C900301	The LNCS-II rainbow DCIP 8λ SpHb SC 400 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
4063 - LNCS-II rainbow DCIP 8λ SpHb SC 1000, Pediatric Sensor	Class IIb C900301	The LNCS-II rainbow DCIP 8λ SpHb SC 1000 reusable sensor is intended for the spot check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B02V001FA			
4067 - LNCS-II rainbow DCI 8λ SpCO, Adult Sensor	Class IIb C900301	The LNCS-II rainbow DCI 8λ SpCO reusable sensor is intended for the spot checking or continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06
4068 - LNCS-II rainbow DCIP 8λ SpCO, Pediatric Sensor	Class IIb C900301	The LNCS-II rainbow DCIP 8λ SpCO reusable sensor is intended for the spot checking or continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06
4069 - LNCS-II rainbow DCI-6 8λ SpCO, Adult Sensor	Class IIb C900301	The LNCS-II rainbow DCI-6 8λ SpCO reusable sensor is intended for the spot checking or continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4070 - LNCS-II rainbow DCIP-6 8λ SpCO, Pediatric Sensor	Class IIb C900301	The LNCS-II rainbow DCIP-6 8λ SpCO reusable sensor is intended for the spot checking or continuous noninvasive monitoring of arterial saturation (SpO ₂), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 08439970000021T1B02V100FD			
4026 - RD rainbow SET – 2 Adt SpHb SpMet, SpO ₂ , PR, PI, PVI, Adult Pulse CO-Oximeter Adhesive Sensor	Class IIb C900301	The RD rainbow SET-2 Adt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
4027 - RD rainbow SET-2 Pdt, SpHb, Adhesive Sensor	Class IIb C900301	The RD rainbow SET-2 Pdt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
4028 - RD rainbow SET-2 Inf, SpHb, Adhesive Sensor	Class IIb C900301	The RD rainbow SET-2 Inf sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
4029 - RD rainbow SET-2 Neo, SpHb, Adhesive Sensor	Class IIb C900301	The RD rainbow SET-2 Neo sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
5306 - RD rainbow Adt 8λ LiDCO SpHb ORI	Class IIb C900301	The RD rainbow SET-2 sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate, methemoglobin saturation (SpMet), and/or total hemoglobin (SpHb).	2026-01-26
Basic UDI-DI: 08439970000021T1B02V101FF			
4034 - RD rainbow Adt 8λ SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Adt 8λ SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
4035 - RD rainbow Pdt 8λ SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Pdt 8λ SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
4036 - RD rainbow Inf 8λ SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Inf 8λ SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
4037 - RD rainbow Neo 8λ SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Neo 8λ SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
Basic UDI-DI: 08439970000021T1B02V102FH			

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Product	Classification and EMDN	Intended use ¹	Date Added
4038 - RD rainbow Adt 12λ SpHb SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Adt 12λ SpHb SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
4039 - RD rainbow Pdt 12λ SpHb SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Pdt 12λ SpHb SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet) and/or total hemoglobin (SpHb).	2025-03-06
4040 - RD rainbow Inf 12λ SpHb SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Inf 12λ SpHb SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
4041 - RD rainbow Neo 12λ SpHb SpCO Adhesive Sensor	Class IIb C900301	The RD rainbow Neo 12λ SpHb SpCO sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin (SpHb).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B02V103FK			
4042 - RD rainbow Lite SET-1 Adt, Adhesive Sensor	Class IIb C900301	The RD rainbow Lite SET-1 Adt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4043 - RD rainbow Lite SET-1 Pdt, Adhesive Sensor	Class IIb C900301	The RD rainbow Lite SET-1 Pdt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4044 - RD rainbow Lite SET-1 Inf, Adhesive Sensor	Class IIb C900301	The RD rainbow Lite SET-1 Inf sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
4045 - RD rainbow Lite SET-1 Neo, Adhesive Sensor	Class IIb C900301	The RD rainbow Lite SET-1 Neo sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V000FK			
2501 - M-LNCS DC-I SpO2, Adult Reusable Finger Clip Sensor, 3 ft	Class IIb C900301	The M-LNCS DC-I reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2502 - M-LNCS DCI-P SpO2, Pediatric Slender Digit, Reusable Finger Clip Sensor, 3 ft	Class IIb C900301	The M-LNCS DCI-P reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V001FM			
2503 - M-LNCS TC-I SpO2, Reusable Ear Sensor, 3 ft	Class IIb C900301	The M-LNCS TC-I reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V002FP			
2504 - M-LNCS TF-I SpO2, Adult Reusable Forehead Sensor, 3 ft	Class IIb C900301	The M-LNCS TF-I reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V003FR			

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Product	Classification and EMDN	Intended use ¹	Date Added
2505 - M-LNCS YI SpO2, Multisite Reusable Sensor, 3 ft	Class IIb C900301	The M-LNCS YI reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V004FT			
2507 - M-LNCS DBI, Adult Soft Reusable Sensor, 3 ft	Class IIb C900301	The M-LNCS DBI reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V100FQ			
2508 - M-LNCS Amtx SpO2, Adult Pulse Oximeter Adhesive Sensor, 18 in	Class IIb C900301	The M-LNCS Amtx sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2509 - M-LNCS Amtx-3 SpO2, Adult Pulse Oximeter Adhesive Sensors, 3 ft	Class IIb C900301	The M-LNCS Amtx-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2510 - M-LNCS Pmtx SpO2, Pediatric Pulse Oximeter Adhesive Sensor, 18 in	Class IIb C900301	The M-LNCS Pmtx sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2511 - M-LNCS Pmtx-3 SpO2, Pediatric Pulse Oximeter Adhesive Sensors, 3 ft	Class IIb C900301	The M-LNCS Pmtx-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2512 - M-LNCS Inf SpO2, Infant Pulse Oximeter Adhesive Sensor, 18 in	Class IIb C900301	The M-LNCS Inf sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2513 - M-LNCS Inf-3 SpO2, Infant Pulse Oximeter Adhesive Sensor, 3 ft	Class IIb C900301	The M-LNCS Inf-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2514 - M-LNCS Neo SpO2, Neonatal/Adult Pulse Oximeter Adhesive Sensor, 18 in	Class IIb C900301	The M-LNCS Neo sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2515 - M-LNCS Neo-3 SpO2, Neonatal/Adult Pulse Oximeter Adhesive Sensor, 3 ft	Class IIb C900301	The M-LNCS Neo-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2516 - M-LNCS NeoPt SpO2, Neonatal Pulse Oximeter Adhesive Sensor	Class IIb C900301	The M-LNCS NeoPt sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2517 - M-LNCS NeoPt-3 SpO2, Neonatal Pulse Oximeter Adhesive Sensor, 3 ft	Class IIb C900301	The M-LNCS NeoPt-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V103FW			
3668 - M-LNCS Neo-L SpO2, Neonatal/Adult Pulse Oximeter Adhesive Sensors, 3 ft	Class IIb C900301	The M-LNCS Neo-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
3669 - M-LNCS NeoPt-L SpO ₂ , Neonatal Pulse Oximeter Adhesive Sensor, 3 ft	Class IIb C900301	The M-LNCS NeoPt-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), and pulse rate (PR).	2025-03-06
3670 - M-LNCS Inf-L SpO ₂ , Infant Pulse Oximeter Adhesive Sensors, 3 ft	Class IIb C900301	The M-LNCS Inf-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V104FY			
2518 - M-LNCS NeoPt-500 SpO ₂ , Neonatal Pulse Oximeter non-Adhesive Sensor	Class IIb C900301	The M-LNCS NeoPt-500 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V105G2			
2919 - M-LNCS E1, SpO ₂ , Adult Single -Patient-Use Ear Sensor	Class IIb C900301	The M-LNCS E1 sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B03V106G4			
3856 - M-LNCS TFA-1, Adult/Pediatric disposable transreflectance forehead sensor, >10 kg	Class IIb C900301	The M-LNCS TFA-1 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V000FW			
1863 - LNCS DC-I SpO ₂ , Adult Reusable Finger Clip Sensor 3ft >30kg	Class IIb C900301	The LNCS DC-I reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
1864 - LNCS DCI-P SpO ₂ , Pediatric/Slender Finger Clip Sensor 3 ft. 10-50kg	Class IIb C900301	The LNCS DCI-P reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V001FY			
1895 - LNCS TC-I SpO ₂ , Reusable Ear Sensor, >30kg, 3 ft	Class IIb C900301	The LNCS TC-I reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V002G2			
1896 - LNCS TF-I SpO ₂ , Adult Reusable Forehead Sensor , LNCS TF-1 & Headband, 3 ft >30kg	Class IIb C900301	The LNCS TF-I reusable sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V003G4			
2258 - LNCS Y-I SpO ₂ , Multisite Reusable Sensor	Class IIb C900301	The LNCS Y-I reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V004G6			

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Product	Classification and EMDN	Intended use ¹	Date Added
2653 - LNCS DB-I SPO2 Adult Soft Reusable Sensor, 3 ft	Class IIb C900301	The LNCS DB-I reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V005G8			
2924 - LNCS DCIv - adult SpO2 Reusable Sensor	Class IIb C900301	The LNCS DCIv reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V100G3			
1859 - LNCS Adtx, SpO2 Adult Pulse Oximeter Adhesive Sensors, 18 in >30kg	Class IIb C900301	The LNCS Adtx sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
1860 - LNCS Pdtx, SpO2 Pediatric Pulse Oximeter Adhesive Sensors, 18 in, 10-50 kg	Class IIb C900301	The LNCS Pdtx sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2317 - LNCS Adtx-3 SpO2, Adult Pulse Oximeter Adhesive Sensors, 3 ft >30kg	Class IIb C900301	The LNCS Adtx-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2318 - LNCS Pdtx-3, SpO2 Pediatric Pulse Oximeter Adhesive Sensors, 3 ft 10-50kg	Class IIb C900301	The LNCS Pdtx-3 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2319 - LNCS Inf-3 SpO2, Infant Pulse Oximeter Adhesive Sensors, 3 ft 3-20kg	Class IIb C900301	The LNCS Inf-3 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2320 - LNCS Neo-3 SpO2, Neonatal/Adult Pulse Oximeter Adhesive Sensors, 3 ft <3kg or >40kg	Class IIb C900301	The LNCS Neo-3 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2321 - LNCS NeoPt-3 SpO2, Neonatal Pulse Oximeter Adhesive Sensor, 3 ft <1kg	Class IIb C900301	The LNCS NeoPt-3 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2328 - LNCS Inf SpO2, Infant Pulse Oximeter Adhesive Sensors, 18 in 3-20kg	Class IIb C900301	The LNCS Inf sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2329 - LNCS Neo SpO2, Neonatal/Adult Pulse Oximeter Adhesive Sensors, 18 in <3kg or >40kg	Class IIb C900301	The LNCS Neo sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2330 - LNCS NeoPt SpO2, Neonatal Pulse Oximeter Adhesive Sensor, 18 in, <1kg	Class IIb C900301	The LNCS NeoPt sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2331 - LNCS NeoPt-500 SpO2, Neonatal Pulse Oximeter Non-Adhesive Sensor, 18 in	Class IIb C900301	The LNCS NeoPt-500 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
2412 - LNCS Newborn SpO ₂ , Neonatal Pulse Oximeter Adhesive Sensor <3kg	Class IIb C900301	The LNCS Newborn SpO ₂ sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
2413 - LNCS Newborn SpO ₂ , Infant/Pediatric Pulse Oximeter Adhesive Sensor	Class IIb C900301	The LNCS Newborn SpO ₂ sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4714 - LNCS Adtx Adhesive Sensor, Philips	Class IIb C900301	The LNCS Adtx is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4715 - LNCS Pdtx/Inf/Neo Sensor, Philips	Class IIb C900301	The LNCS Pdtx/Inf/Neo sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
5265 - LNCS Neo Newborn Adhesive Sensor, 20/Box, Masimo	Class IIb C900301	The LNCS Neo Newborn SpO ₂ sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-06-05
Basic UDI-DI: 084399700000Z1T1B04V101G5			
1861 - LNCS Inf-L, Infant Pulse Oximeter Adhesive Sensors, 3-20 kg ft	Class IIb C900301	The LNCS Inf-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
1862 - LNCS Neo-L SpO ₂ , Neonatal/Adult Pulse Oximeter Adhesive Sensors, 3 ft, <3kg or > 40kg	Class IIb C900301	The LNCS Neo-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
1901 - LNCS NeoPt-L SpO ₂ , Neonatal Pulse Oximeter Sensor, 3 ft, <1kg	Class IIb C900301	The LNCS NeoPt-L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V102G7			
2411 - LNCS Trauma SpO ₂ , Adult Pulse Oximeter Adhesive Sensor	Class IIb C900301	The LNCS Trauma sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V103G9			
2601 - LNCS Adtx-3 SpO ₂ Adult Pulse Oximeter Adhesive Sensor 3 ft Sterile	Class IIb C900301	The LNCS Adtx-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
2602 - LNCS Pdtx-3 SpO ₂ , Pediatric Pulse Oximeter Adhesive Sensor 3 ft Sterile	Class IIb C900301	The LNCS Pdtx-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
2603 - LNCS Inf-3 SpO ₂ Infant Pulse Oximeter Adhesive Sensor 3 ft Sterile	Class IIb C900301	The LNCS Inf-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
2604 - LNCS Neo-3 SpO ₂ , Neonatal/Adult Pulse Oximeter Adhesive Sensors, 3 ft Sterile	Class IIb C900301	The LNCS Neo-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
2605 - LNCS NeoPt-3 SpO ₂ , Neonatal Pulse Oximeter Adhesive Sensor, 3 ft (Sterile EO) 3 ft	Class IIb C900301	The LNCS NeoPt-3 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
2606 - LNCS NeoPt-500 SpO ₂ , Neonatal Pulse Oximeter Non-Adhesive Sensor, 3 ft (Sterile EO)	Class IIb C900301	The LNCS NeoPt-500 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V104GB			
2918 - LNCS E1, SpO ₂ , Adult Pulse Oximeter Adhesive Sensor	Class IIb C900301	The LNCS E1 sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V105GD			
3858 - LNCS TFA-1, Adult/Pediatric disposable transreflectance sensor, >10 kg	Class IIb C900301	The LNCS TFA-1 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B04V106GF			
3857 - LNCS-Red TFA-1 SpO ₂ Adult/Pediatric Disposable Transreflectance sensor, >10kg	Class IIb C900301	The LNCS-Red TFA-1 sensor is intended for the noninvasive spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B06V100GR			
4582 - Radius PPG Adt Adhesive Sensor	Class IIb C900301	The Radius PPG Adt is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4583 - Radius PPG Pdt	Class IIb C900301	The Radius PPG Pdt is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4584 - Radius PPG Inf	Class IIb C900301	The Radius PPG Inf is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4585 - Radius PPG Neo Adhesive Sensor	Class IIb C900301	The Radius PPG Neo is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
4935 - Masimo Sensor	Class IIb C900301	The Masimo Sensor is intended to support the spot-checking or continuous monitoring of functional oxygen saturation (SpO ₂) and Pulse Rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B06V101GT			
9954 - Radius PPG, Adult	Class IIb Z1203020408	The Radius PPG, Adt is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
9955 - Radius PPG, Adult	Class IIb Z1203020408	The Radius PPG, Adt is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B07V000GX			
1778 - SPO2.COM RS-I, Adult SpO ₂ Reusable Sensor	Class IIb C900301	The SPO2.COM RS-I sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO ₂) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z1T1B07V100H4			
1774 - SPO2.COM A, Adult SpO2 disposable Sensor	Class IIb C900301	The SPO2.COM sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
1775 - SPO2.COM P, Pediatric SpO2 disposable Sensor	Class IIb C900301	The SpO2.COM sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
1776 - SPO2.COM N, Neonatal SpO2 disposable Sensor	Class IIb C900301	The SPO2.COM sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
1777 - SPO2.COM I, Infant SpO2 disposable Sensor	Class IIb C900301	The SPO2.COM sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V001G2			
2069 - rainbow DCI-P-dc3, SpCO, SpMet, SpO2, Pediatric/Slender digit Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCI-P-dc3 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2070 - rainbow DCIP-dc12 SpO2 SpMet SpO2 Pediatric/Slender Digit, Direct Connect Reusable Sensor 12 ft	Class IIb C900301	The rainbow DCIP-dc12 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2201 - rainbow DCI-dc3, SpO2, SpCO, SpMet, Adult Direct Connect Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCIP-dc12 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2202 - rainbow DCI-dc3 - SpCO SpMet SpO2, Adult Direct Connect Reusable Sensor, 12 ft	Class IIb C900301	The rainbow DCIP-dc3 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2407 - rainbow DCI-dc8 SpCO SpMet SpO2 Adult, Direct Connect Reusable Sensor, 8 ft	Class IIb C900301	The rainbow DCI-dc8 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2640 - rainbow DCIP-dc8 SpO2, SpMet, SpO2 Pediatric/ Slender digit, Direct Connect Reusable Sensor, 8 ft	Class IIb C900301	The rainbow DCIP-dc8 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V002G4			
2696 - rainbow DCI, SpCO, SpMet, SpO2 Adult, Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCI reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2697 - rainbow DCI-P, SpCO, SpMet, SpO2, Pediatric/Slender digit Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCI-P reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
3657 - rainbow DCI-6, SpO2, SpCO and SpMet, Adult Reusable Sensor, 6 ft	Class IIb C900301	The rainbow DCI-6 reusable sensor is intended for the spot-checking or continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06
3658 - rainbow DCI-P-6, SpO2, SpCO and SpMet, Pediatric/Slender digit Reusable Sensor, 6 ft	Class IIb C900301	The rainbow DCI-P-6 reusable sensor is intended for the spot-checking or continuous noninvasive monitoring of arterial saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V003G6			
3797 - rainbow DCI-mini SC-200, Reusable Sensor (SpHb, SpO2 and SpMet), 200 SpHb Spot checks	Class IIb C900301	The rainbow DCI-mini SC-200 reusable sensor is intended for the noninvasive spot-check and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR) and the spot-checking of total hemoglobin concentration (SpHb).	2025-03-06
3798 - rainbow DCI-mini SC-400, Reusable Sensor (SpHb, SpO2 and SpMet), 400 SpHb Spot checks	Class IIb C900301	The rainbow DCI-mini SC-400 reusable sensor is intended for the noninvasive spot-check and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR) and the spot-checking of total hemoglobin concentration (SpHb).	2025-03-06
3799 - rainbow DCI-mini SC-1000, Reusable Sensor (SpHb, SpO2 and SpMet), 1000 SpHb Spot checks	Class IIb C900301	The rainbow DCI-mini SC-1000 reusable sensor is intended for the noninvasive spot-check and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR) and the spot-checking of total hemoglobin concentration (SpHb).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V004G8			
4309 - rainbow Super DCI-mini SC-200, Reusable Sensor	Class IIb C900301	The rainbow Super DCI-mini SC-200 reusable sensor is intended for the noninvasive spot check monitoring of arterial saturation (SpO2), total hemoglobin (SpHb), arterial carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and pulse rate.	2025-03-06
4310 - rainbow Super DCI-mini SC-400, Reusable Sensor	Class IIb C900301	The rainbow Super DCI-mini SC-400 reusable sensor is intended for the noninvasive spot check monitoring of arterial saturation (SpO2), total hemoglobin (SpHb), arterial carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and pulse rate.	2025-03-06
4311 - rainbow Super DCI-mini SC-1000, Reusable Sensor	Class IIb C900301	The rainbow Super DCI-mini SC-1000 reusable sensor is intended for the noninvasive spot check monitoring of arterial saturation (SpO2), total hemoglobin (SpHb), arterial carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and pulse rate.	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V100G5			
2219 - R25-L, SpO2, SpCO, SpMet, Adult/ Neonatal Pulse CO-Oximeter Adhesive Sensor	Class IIb C900301	The R25-L sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2221 - R25, SpO2, SpCO, SpMet, Adult Pulse CO-Oximeter Adhesive Sensor	Class IIb C900301	The R25 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
2222 - R20, SpO2, SpCO, SpMet, Pediatric, Pulse CO-Oximeter Adhesive Sensor	Class IIb C900301	The R20 sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z1T1B13V101G7			
2414 - R1 25L, SpO2, SpHb, SpMet, Adult / Neonatal Pulse Oximeter Adhesive Sensor	Class IIb C900301	The R1 25L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb).	2025-03-06
2415 - R1 20L, SpO2, SpHb, SpMet, Infant Pulse Oximeter Adhesive Sensor	Class IIb C900301	The R1 20L sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb).	2025-03-06
3792 - R1 25, SpO2, SpHb, SpMet, Adult Pulse CO-Oximeter Adhesive Sensors	Class IIb C900301	The R1 25 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb).	2025-03-06
3793 - R1 20, SpO2, SpHb, SpMet, Pediatric / Slender Digit, Pulse CO-Oximeter Adhesive Sensors	Class IIb C900301	The R1 20 sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B13V102G9			
2220 - rainbow R20-L, SpO2, SpCO, SpMet, Infant Pulse CO-Oximeter Adhesive Sensor	Class IIb C900301	The rainbow R20-L sensor is intended for the continuous noninvasive monitoring of arterial oxygen saturation (SpO2), arterial carboxyhemoglobin saturation (SpCO), arterial methemoglobin (SpMet) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B14V000GB			
1396 - DCSC, SpO2 Adult Reusable Sensor, 3 ft	Class IIb C900301	The Direct Connect Reusable Adult Sensors are intended for the spot-checking and continuous monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
1969 - DC-12, SpO2, Adult Reusable Sensor, 12 ft	Class IIb C900301	The DC-12 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2387 - DC-8 SpO2, Adult Reusable Sensor 8 ft	Class IIb C900301	The DC-8 sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B14V001GD			
2651 - DB-I-dc3, SpO2, Adult Reusable Sensor, 3 ft	Class IIb C900301	The DB-I-dc3 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2652 - DB-dc8 ,SpO2, Adult Reusable Sensor- 8 ft	Class IIb C900301	The DB-dc8 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B15V000GN			
2646 - rainbow DC-3 SC-200 - SpHb SpO2 SpMet 200 spot checks Adult Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DC-3 SC-200 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
2647 - rainbow DCP-3 SC-200 - SpHb SpO2 SpMet 200 spot checks, Pediatric/Slender digit Reusable Sensor	Class IIb C900301	The rainbow DCP-3 SC-200 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
3418 - rainbow DCI SC-200, SpHb, SpO2, SpMet, 200 Spot checks, Adult Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCI SC-200 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb) and pulse rate (PR).	2025-03-06
3419 - rainbow DCIP SC-200,SpHb, SpO2 , SpMet, 200 Spot checks, Pediatric/Slender digit, Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCIP SC-200 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb) and pulse rate (PR).	2025-03-06
3420 - rainbow DCI SC-400, SpHb, SpO2 , SpMet, 400 Spot checks, Adult Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCIP SC-400 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb) and pulse rate (PR).	2025-03-06
3421 - rainbow DCIP SC-400,SpHb, SpO2 ,SpMet , 400 Spot checks, Pediatric/Slender digit, Reusable Sensor, 3 ft	Class IIb C900301	The rainbow DCIP SC-400 reusable sensor is intended for the spot-check and continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb) and pulse rate (PR).	2025-03-06
3647 - rainbow DCI SC-1000, SpHb, SpO2 , SpMet,1000 Spot checks, Adult Reusable Sensor, 3 ft,	Class IIb C900301	The rainbow DCI SC-1000 reusable sensor is intended for the spot-check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
3648 - rainbow DCIP SC-1000, SpHb, SpO2 , SpMet, 1000 Spot checks Pediatric/Slender Digit, Reusable Sensor, 3 ft,	Class IIb C900301	The rainbow DCIP SC-1000 reusable sensor is intended for the spot-check or continuous noninvasive monitoring of arterial saturation (SpO2), arterial methemoglobin (SpMet), total hemoglobin (SpHb), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B16V000GZ			
4325 - Rad-G Reusable Sensor	Class IIb C900301	The Rad-G reusable sensor is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B16V001H3			
4653 - Rad-G YI Multisite Reusable Sensor	Class IIb C900301	The Rad-G YI Multisite Reusable Sensor is intended for the continous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B18V000HP			
2053 - Red DCI-dc3 SpO2, Adult Reusable Sensor, 3 ft	Class IIb C900301	The Red DCI-dc3 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2054 - Red DCI-dc12 SpO2, Adult Reusable Sensor 12 ft	Class IIb C900301	The Red DCI-dc12 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
2256 - Red DCIP-dc3, SpO2 Pediatric Reusable Sensor, 3 ft	Class IIb C900301	The Red DCIP-dc3 sensor is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
2257 - Red DCIP-dc12 - SpO2 Pediatric Reusable Sensor	Class IIb C900301	The Red DCIP-dc12 reusable sensor is intended for the spot-checking and continuous noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T1B18V001HR			
2643 - Red DBI-dc3, SpO2, Adult Reusable Sensor, 3 ft	Class IIb C900301	The RED DBI-dc3 reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
2644 - Red DBI-dc8 SpO2 Adult Reusable Sensor-8 ft	Class IIb C900301	The RED DBI-dc8 reusable sensor is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T2A17V000HE			
9707 - MightySat Rx (Fingertip Pulse Oximeter, CE)	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
9807 - MightySat Rx (fingertip pulse oximeter w/Bluetooth, CE)	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
9809 - MightySat, Bluetooth, Rx, US	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T2A17V001HG			
9901 - MightySat (fingertip pulse oximeter, Bluetooth, PVI, RRp)	Class IIb Z1203020408	The MightySat Fingertip Pulse Oximeter is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), and respiration rate from the Pleth (RRp).	2025-03-06
9907 - MightySat Rx (fingertip pulse oximeter w/Bluetooth, PVI, RRp, CE)	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is intended for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T2A17V002HJ			
95162 - MightySat Rx	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and respiration rate from the pleth (RRp).	2025-06-05
95166 - MightySat Rx	Class IIb Z1203020408	The MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and respiration rate from the pleth (RRp).	2025-06-05
Basic UDI-DI: 084399700000Z1T2A21V000FR			
95123 - Stork Camera	Class IIb Z1203020280	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in hospital and home environments.	2023-12-13
95124 - Stork Hub	Class IIb Z1203020280	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in hospital and home environments.	2023-12-13
95125 - Stork Sensor	Class IIb Z1203020202	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in hospital and home environments.	2023-12-13

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z1T2A21V001FT			
95121 - Stork Vitals+	Class IIb Z1203020202	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork™ is intended to be used in home environments.	2024-08-26
95122 - Stork Vitals	Class IIb Z1203020202	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork™ is intended to be used in home environments.	2024-08-26
Basic UDI-DI: 084399700000Z1T3A02V000FV			
9183 - Radical-7 (Bluescreen Handheld, Refurbished)	Class IIb Z1203020202	The Radical-7 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), total hemoglobin (SpHb), and methemoglobin saturation (SpMet).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A02V001FX			
9500 - Radical-7 Color Screen, Handheld	Class IIb Z1203020202	The Radical-7 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa), and Respiratory Rate from photoplethysmogram (RRp).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A06V000H9			
4820 - Masimo Sleep	Class IIb Z1203020408	Masimo Sleep is intended to monitor the functional arterial oxygen (SpO2), pulse rate (PR), Respiration Rate (RRp), and PVi during sleep.	2025-03-06
Basic UDI-DI: 084399700000Z1T3A12V000GA			
9794 - Rad-67, Pulse CO-Oximeter (Spot-check)	Class IIb Z1203020408	The Masimo Rad-67 and Accessories are intended for the non-invasive spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), total hemoglobin concentration (SpHb), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A13V000GM			
9196 - Rad-5 (Handheld)	Class IIb Z1203020408	The Rad-57 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9198 - Rad-5 (Handheld, with Sensor Sample Pack)	Class IIb Z1203020408	The Rad-5 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9214 - Rad-5 (Handheld, International)	Class IIb Z1203020408	The Rad-5 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9234 - Rad-5 (Handheld, Refurbished)	Class IIb Z1203020408	The Rad-5 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A14V000GY			
9197 - Rad-5v (Handheld)	Class IIb Z1203020408	The Rad-5v and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
9199 - Rad-5v (Handheld, with Sensor Sample Pack)	Class IIb Z1203020408	The Rad-5v and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9215 - Rad-5v (Handheld, International)	Class IIb Z1203020408	The Rad-5v and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9235 - Rad-5v (Handheld, Refurbished)	Class IIb Z1203020408	The Rad-5v and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9540 - Rad-5v (Handheld, Pediatric)	Class IIb Z1203020408	The Rad-5v and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
9711 - Rad-5v (Handheld, Adult)	Class IIb Z1203020408	The Rad-5v is intended for the noninvasive continuous monitoring functional saturation of arterial oxygen hemoglobin (SpO2), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A15V000HB			
9062 - Rad-57cm, Handheld, Rainbow DCI-dc3/DCIP-dc3	Class IIb Z1203020408	The Rad-57 and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
9179 - Rad-57c (Handheld, Refurbished)	Class IIb Z1203020408	The Rad-57c and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
9180 - Rad-57cm (Handheld, Refurbished)	Class IIb Z1203020408	The Rad-57cm and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A15V001HD			
3734 - Rad-57 Handheld, Rainbow DCI/RC-1 Cable/Case /EMS Pkg 1	Class IIb Z1203020408	The Rad-57 and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
3735 - Rad-57 Handheld, Rainbow DCI/DCIP/RC-1 Cable /Case/EMS Pkg 2	Class IIb Z1203020408	The Rad-57 and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
3736 - Rad-57 Handheld, Rainbow DCI/DCIP/RC-1 Cable/Case/EMS Pkg 3	Class IIb Z1203020408	The Rad-57 and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06
3737 - Rad-57 Handheld, Rainbow DCI/DCIP/RC-1 Cable/Case EMS Pkg 4	Class IIb Z1203020408	The Rad-57 and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
9216 - Rad-57 (Handheld)	Class IIb Z1203020408	The Rad-57 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO) and/or methemoglobin saturation (SpMet).	2025-03-06
9217 - Rad-57 (Handheld, Configurable, Refurbished)	Class IIb Z1203020408	The Rad-57 and accessories are intended for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), total hemoglobin concentration (SpHb), carboxyhemoglobin saturation (SpCO) and/or methemoglobin saturation (SpMet).	2025-03-06
Basic UDI-DI: 084399700000Z1T3A16V000HN			
3580 - Pronto, (DCI SC-200)	Class IIb Z1203020408	The Pronto and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
3581 - Pronto, (DCIP SC-200)	Class IIb Z1203020408	The Pronto and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
3582 - Pronto, (DCI SC-400)	Class IIb Z1203020408	The Pronto and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
3583 - Pronto, (DCIP SC-400)	Class IIb Z1203020408	The Pronto and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
3584 - Pronto, (DCI SC-200, DCIP SC-200)	Class IIb Z1203020408	The Pronto and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
4175 - Pronto, Unlimited	Class IIb Z1203020408	The Pronto Pulse CO-Oximeter and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate, and total hemoglobin concentration (SpHb).	2025-03-06
9167 - Pronto, Alt Care	Class IIb Z1203020408	The Pronto, Alt Care and Accessories are intended for the noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate, and total hemoglobin concentration (SpHb).	2025-03-06
9757 - Pronto (Next Generation, SpHb)	Class IIb Z1203020408	The Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories are intended for the noninvasive spot-checking of functional saturation of arterial oxygen hemoglobin (SpO ₂), pulse rate (PR), and total hemoglobin concentration (SpHb).	2025-03-06
Basic UDI-DI: 084399700000Z1T3B16V000J7			
9849 - Rad-G Pulse Oximeter continuous version	Class IIb Z1203020408	The Rad-G and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), Pulse Rate (PR), and Pleth Respiration Rate (RRp).	2025-03-06
Basic UDI-DI: 084399700000Z1T3B16V001J9			
9847 - Rad-G Pulse Oximeter continuous version with sensor	Class IIb Z1203020408	The Rad-G and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), Pulse Rate (PR), and Pleth Respiration Rate (RRp).	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 084399700000Z1T3B16V002JB			
4469 - Rad-G Pulse Oximeter	Class IIb Z1203020408	The Rad-G Pulse Oximeter is intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T4A07V000J7			
99030 - iSpO2 Rx Pulse Oximeter, USB-C, Adult	Class IIb Z1203020408	The iSpO2 Rx Pulse Oximeter is intended for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
99031 - iSpO2 Rx Pulse Oximeter, USB-C, Pediatric	Class IIb Z1203020408	The iSpO2 Rx Pulse Oximeter is intended for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
99032 - iSpO2 Rx Pulse Oximeter, USB-C, RD	Class IIb Z1203020408	The iSpO2 Rx Pulse Oximeter is intended for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T4A08V000JJ			
3914 - Masimo SET Intellivue Module (Philips)	Class IIb Z1203020408	The Masimo SET Intellivue Module and Accessories are intended for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
3915 - Masimo SET Intellivue Module (Masimo)	Class IIb Z1203020408	The Masimo SET Intellivue Module and Accessories are intended for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T4A08V001JL			
3777 - Masimo, rainbow SET Intellivue Module	Class IIb Z1203020408	The Masimo rainbow SET Intellivue Module and Accessories are intended for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and respiratory rate (RRa).	2025-03-06
3924 - Masimo rainbow SET Intellivue Module	Class IIb Z1203020408	The Masimo rainbow SET Intellivue Module and Accessories are intended for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and respiratory rate (RRa).	2025-03-06
Basic UDI-DI: 084399700000Z1T4A09V000JV			
4182 - rainbow SET Pulse CO-Oximetry Cable, Carescape SpO2, Masimo, 0.9m Cable	Class IIb Z1203020408	The CARESCAPE SpO2 – Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for the continuous noninvasive monitoring of arterial oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa),	2025-03-06
4183 - rainbow SET Pulse CO-Oximetry Cable, GE Carescape SpO2, 0.9 m Cable	Class IIb Z1203020408	The CARESCAPE SpO2 – Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for the continuous noninvasive monitoring of arterial oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa),	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4184 - rainbow SET Pulse CO-Oximetry Cable, GE Carescape SpO2	Class IIb Z1203020408	The CARESCAPE SpO2 – Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for the continuous noninvasive monitoring of arterial oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa),	2025-03-06
4234 - rainbow SET Pulse CO-Oximetry Cable, GE Carescape SpO2, Masimo	Class IIb Z1203020408	The CARESCAPE SpO2 – Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for the continuous noninvasive monitoring of arterial oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa),	2025-03-06
Basic UDI-DI: 084399700000Z1T4A10V000G7			
99028 - Masimo SET Module	Class IIb Z1203020408	The Masimo SET Module is intended for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
99028 - Masimo SET Module, RD	Class IIb Z1203020408	The Masimo SET Module is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
99029 - Masimo SET Module	Class IIb Z1203020408	The Masimo SET Module is intended for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
99029 - Masimo SET Module, LNC	Class IIb Z1203020408	The Masimo SET Module is intended for the spot-checking and continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).	2025-03-06
Basic UDI-DI: 084399700000Z1T4A18V000JX			
4313 - Rainbow SET Module	Class IIb Z1203020408	The Rainbow SET Module is intended to be used with Welch Allyn Platform series patient monitoring instruments for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, SpHb and RRa.	2023-05-06
4331 - Rainbow Set Module for Welch Allyn	Class IIb Z1203020408	The Rainbow SET Module is intended to be used with Welch Allyn Platform series patient monitoring instruments for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, SpHb and RRa.	2025-03-06
4513 - Rainbow Set Module	Class IIb Z1203020408	The Rainbow SET Module is intended to be used with Welch Allyn Platform series patient monitoring instruments for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, SpHb and RRa.	2025-03-06
Basic UDI-DI: 084399700000Z1T5A02V000H3			
9021 - Radical Docking Station, RDS-1	Class IIb Z1203020280	The Radical Docking Station, RDS-1, is an accessory for use with Radical-7 intended to support continuous patient monitoring of the Radical-7.	2024-12-19
9023 - Radical Docking Station, RDS-3	Class IIb Z1203020280	The Radical Docking Station, RDS-3, is an accessory for use with Radical-7 intended to support continuous patient monitoring of the Radical-7.	2024-12-19
9171 - Radical Docking Station RDS-3 (Refurbished)	Class IIb Z1203020280	The Radical Docking Station, RDS-3, is an accessory for use with Radical-7 intended to support continuous patient monitoring of the Radical-7.	2024-12-19

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Product	Classification and EMDN	Intended use ¹	Date Added
9172 - Radical Docking Station RDS-1 (Refurbished)	Class IIb Z1203020408	The Radical Docking Station, RDS-1, is an accessory for use with Radical-7 intended to support continuous patient monitoring of the Radical-7.	2024-12-19
Basic UDI-DI: 084399700000Z1T5B06V000JY			
4586 - Radius PPG Reusable Chip	Class IIb Z1203020408	The Radius PPG Reusable Chip is an accessory to the Radius PPG that is intended for the transmission of measured pulse oximetry data from the Radius PPG to a monitoring device.	2025-03-06
4587 - Radius PPG Wireless Receiver M20	Class IIb Z1203020408	The Radius PPG Wireless Receiver M20 is an accessory to the Radius PPG that is intended for the transmission of measured pulse oximetry data from the Radius PPG to a monitoring device.	2025-03-06
4588 - Radius PPG Wireless Receiver MD20	Class IIb Z1203020408	The Radius PPG Wireless Receiver MD20 is an accessory to the Radius PPG that is intended for the transmission of measured pulse oximetry data from the Radius PPG to a monitoring device.	2025-03-06
4589 - Radius PPG Wireless Receiver R25	Class IIb Z1203020408	The Radius PPG Wireless Receiver R25 is an accessory to the Radius PPG that is intended for the transmission of measured pulse oximetry data from the Radius PPG to a monitoring device.	2025-03-06
5276 - Masimo SafetyNet, Radius PPG Chip	Class IIb Z1203020408	The Radius PPG Reusable Chip is an accessory to the Radius PPG that is intended for the transmission of measured pulse oximetry data from the Radius PPG to a monitoring device.	2025-06-05
Basic UDI-DI: 084399700000Z2T1B05V100HB			
3401 - RAS-125c, Short Term, Acoustic Respiration Cloth Sensor, Adult, 10/Box, Masimo	Class IIb Z12030285	The RAS-125c sensor is intended for the continuous noninvasive monitoring of respiratory rate (RRa).	2025-06-05
3475 - RAS-125c, Adult/Pediatric Acoustic Respiration cloth sensor (RRa)	Class IIb Z12030285	The RAS-125c sensor is intended for the continuous noninvasive monitoring of respiratory rate (RRa).	2024-10-02
3483 - RAS-125c, Short Term, Acoustic Respiration Cloth Sensor, Adult/Ped, 10/Box, Masimo	Class IIb Z12030285	The RAS-125c sensor is intended for the continuous noninvasive monitoring of respiratory rate (RRa).	2024-10-02
Basic UDI-DI: 084399700000Z2T1B05V101HD			
4171 - RAS-45, RRa, Adult/Pediatric Acoustic Respiration Sensors	Class IIb Z12030285	The RAD-45 sensor is intended for the continuous, noninvasive monitoring of respiratory rate (RRa).	2024-10-02
4425 - RAS-45 Inf/Neo rainbow Acoustic Sensor, Masimo	Class IIb Z12030285	The RAS-45 Inf/Neo is indicated for continuous, noninvasive monitoring of respiratory rate (RRa).	2024-10-02
4828 - Radius VSM RAS-45 Acoustic Respiration Sensor, Adult	Class IIb Z12030285	The Radius VSM RAS-45 is intended for the continuous noninvasive monitoring of respiratory rate (RRa).	2024-10-02
Basic UDI-DI: 084399700000Z3T4D01V000KJ			
4199 - Nomoline ISA CO ₂ , Masimo D8, Sidestream Gas Analyzer	Class IIb R020108	The Nomoline ISA CO ₂ Module and Accessories are intended to be connected to other medical backboard devices for monitoring of breath rate and CO ₂ . The Nomoline ISA CO ₂ Module and Accessories are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4410 - Nomoline ISA CO2, DB9	Class IIb R020108	The Nomoline ISA CO2 Module and Accessories are intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline ISA CO2 Module and Accessories are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.	2025-03-06
4412 - Nomoline ISA CO2, LEMO	Class IIb R020108	The Nomoline ISA CO2 Module and Accessories are intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline ISA CO2 Module and Accessories are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.	2025-03-06
4427 - Nomoline ISA CO2, Philips	Class IIb R020108	The Nomoline ISA CO2 Module and Accessories are intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline ISA CO2 Module and Accessories are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.	2025-03-06
9921 - Nomoline ISA CO2	Class IIb R020108	The Nomoline ISA CO2 Module and Accessories are intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline ISA CO2 Module and Accessories are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.	2025-03-06
Basic UDI-DI: 084399700000Z3T4D03V000L8			
4428 - IRMA CO2	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2023-05-10
4429 - IRMA CO2, Root	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2025-06-05
4495 - IRMA CO2	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2023-05-10
4748 - IRMA CO2	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2023-05-10
4749 - IRMA CO2	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2023-05-10
4750 - IRMA CO2	Class IIb Z1203020499	The IRMA CO2 mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and inspired/expired gases during anesthesia, recovery and respiratory care.	2023-05-10
Basic UDI-DI: 084399700000Z3T4D03V001LA			
4430 - IRMA AX+, Root	Class IIb Z1203020499	The IRMA AX+ Capnograph mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and the breathing gases CO2, N2O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.	2025-06-05

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Product	Classification and EMDN	Intended use ¹	Date Added
4767 - IRMA AX+	Class IIb Z1203020499	The IRMA AX+ Capnograph mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and the breathing gases CO ₂ , N ₂ O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.	2023-05-10
4768 - IRMA AX+	Class IIb Z1203020499	The IRMA AX+ Capnograph mainstream gas analyzer is intended to be connected to other medical devices and a patient breathing circuit for the monitoring of breath rate and the breathing gases CO ₂ , N ₂ O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.	2023-05-10
Basic UDI-DI: 084399700000Z3T4D04V000LK			
4414 - NomoLine ISA OR+	Class IIb Z1203020499	The NomoLine ISA OR+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , O ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
4416 - NomoLine ISA OR+	Class IIb Z1203020499	The NomoLine ISA OR+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , O ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
9922 - NomoLine ISA OR+	Class IIb Z1203020499	The NomoLine ISA OR+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , O ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
Basic UDI-DI: 084399700000Z3T4D04V001LM			
4417 - NomoLine ISA AX+	Class IIb Z1203020499	The NomoLine ISA AX+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
4419 - NomoLine ISA AX+	Class IIb Z1203020499	The NomoLine ISA AX+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
9923 - NomoLine ISA AX+	Class IIb Z1203020499	The NomoLine ISA AX+ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and the following breathing gases: CO ₂ , N ₂ O, Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane.	2023-05-10
Basic UDI-DI: 084399700000Z3T4D04V002LP			
4412 - NomoLine ISA CO ₂	Class IIb Z1203020499	The NomoLine ISA CO ₂ sidestream gas analyzer and accessories is intended to be connected to other medical backboard devices and a patient breathing circuit for the monitoring of breath rate and CO ₂ .	2023-05-10
Basic UDI-DI: 084399700000Z3T5D03V000LT			

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Product	Classification and EMDN	Intended use ¹	Date Added
106220 - IRMA Airway Adapter (Adult, Pediatric)	Class IIa Z1203020480		2023-05-10
106260 - IRMA Airway Adapter Infant	Class IIa Z1203020480		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V000M6			
3801 - NomoLine Adult/Pediatric Airway Adapter Set with Luer	Class IIa R020108		2023-05-10
3814 - NomoLine LH Adult/Pediatric Airway Adapter Set	Class IIa R020108		2023-05-10
3815 - NomoLine LH Adult/Pediatric Airway Adapter Set 3m	Class IIa R020108		2023-05-10
3816 - NomoLine LH Infant Airway Adapter Set	Class IIa R020108		2023-05-10
3827 - NomoLine HH Adult/Pediatric Airway Adapter Set	Class IIa R020108		2023-05-10
3828 - NomoLine HH Adult/Pediatric Airway Adapter Set 3m	Class IIa R020108		2023-05-10
4367 - NomoLine HH Infant/Neonatal Airway Adapter Set	Class IIa R020108		2023-05-10
4620 - NomoLine LH Adult/Pediatric Airway Adapter Set 4m	Class IIa R020108		2023-05-10
4989 - NomoLine HH Adult/Pediatric Airway Adapter Set, 4m	Class IIa R020108		2023-05-10
4991 - NomoLine HH Infant/Neonatal Airway Adapter Set, 4m, 25/box	Class IIa R020108		2025-08-22
Basic UDI-DI: 084399700000Z3T5D04V001M8			
3805 - NomoLine Pediatric Nasal CO2 Cannula with Luer	Class IIa R020108		2023-05-10
3806 - NomoLine Infant Nasal CO2 Cannula with Luer	Class IIa R020108		2023-05-10
3817 - NomoLine LH Adult Nasal CO2 Cannula	Class IIa R020108		2023-05-10
3818 - NomoLine LH Pediatric Nasal CO2 Cannula	Class IIa R020108		2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
3819 - NomoLine LH Infant Nasal CO2 Cannula	Class IIa R020108		2023-05-10
3830 - NomoLine HH Adult Nasal CO2 Cannula	Class IIa R020108		2023-05-10
3831 - NomoLine HH Pediatric Nasal CO2 Cannula	Class IIa R020108		2023-05-10
3832 - NomoLine HH Infant Nasal CO2 Cannula	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V002MA			
3809 - NomoLine Adult Nasal/Oral CO2 Cannula with Luer	Class IIa R020108		2023-05-10
3810 - NomoLine Pediatric Nasal/Oral CO2 Cannula with Luer	Class IIa R020108		2023-05-10
3822 - NomoLine LH Adult Nasal/Oral CO2 Cannula	Class IIa R020108		2023-05-10
3823 - NomoLine LH Pediatric Nasal/Oral CO2 Cannula	Class IIa R020108		2023-05-10
3835 - NomoLine HH Adult Nasal/Oral CO2 Cannula	Class IIa R020108		2023-05-10
4626 - NomoLine LH Adult Nasal/Oral CO2 Cannula 4m	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V003MC			
3813 - NomoLine Adult Single Nasal Progn CO2 Cannula with Luer	Class IIa R020108		2023-05-10
3826 - NomoLine LH Adult Single Nasal Prong CO2 Cannula	Class IIa R020108		2023-05-10
3829 - NomoLine HH Infant Airway Adapter Set	Class IIa R020108		2023-05-10
3839 - NomoLine HH Adult Single Nasal Prong CO2 Cannula	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V004ME			
3807 - NomoLine Adult Nasal CO2 Cannula with O2 and Luer	Class IIa R020108		2023-05-10
3808 - NomoLine Pediatric Nasal CO2 Cannula with O2 and Luer	Class IIa R020108		2023-05-10
3820 - NomoLine LH Adult Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
3821 - NomoLine LH Pediatric Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
3833 - NomoLine HH Adult Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
3834 - NomoLine HH Pediatric Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
4624 - NomoLine LH Adult Nasal CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4933 - NomoLine HH Infant Nasal CO2 Cannula with O2, 4m	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V005MG			
3811 - NomoLine Adult Nasal/Oral CO2 Cannula with O2 and Luer	Class IIa R020108		2023-05-10
3812 - NomoLine Pediatric Nasal/Oral CO2 Cannula with O2 and Luer	Class IIa R020108		2023-05-10
3824 - NomoLine LH Adult Nasal/Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
3825 - NomoLine LH Pediatric Nasal/Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
3837 - NomoLine HH Adult Nasal/Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
3838 - NomoLine HH Pediatric Nasal/Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
4628 - NomoLine LH Adult Nasal/Oral CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4629 - NomoLine LH Pediatric Nasal/Oral CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4968 - NomoLine HH Adult Nasal/Oral CO2 Cannula with O2, 4m	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D04V010M9			
3800 - Nomoline HH Multi-Patient Use Adapter	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D05V000MH			
4449 - NomoLine-O HH Adult/Pediatric Airway Adapter Set	Class IIa R020108		2023-05-10
4450 - NomoLine-O HH Infant/Neonatal Airway Adapter Set	Class IIa R020108		2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
4454 - NomoLine-O LH Adult/Pediatric Airway Adapter Set	Class IIa R020108		2023-05-10
4630 - Nomoline-O LH Adult/Pediatric Airway Adapter Set	Class IIa R020108		2023-05-10
4990 - NomoLine-O HH Adult/Pediatric Airway Adapter Set, 4m, 25/box	Class IIa R020108		2025-06-05
4992 - NomoLine-O HH Infant/Neonatal Airway Adapter Set, 4m, 25/box	Class IIa R020108		2025-08-22
Basic UDI-DI: 084399700000Z3T5D05V001MK			
4455 - NomoLine-O LH Adult Nasal CO2 Cannula	Class IIa R020108		2023-05-10
4641 - NomoLine-O LH Pediatric Nasal CO2 Cannula	Class IIa R020108		2023-05-10
4643 - NomoLine-O HH Adult Nasal CO2 Cannula	Class IIa R020108		2023-05-10
4662 - NomoLine-O LH Infant Nasal CO2 Cannula	Class IIa R020108		2023-05-10
4664 - NomoLine-O HH Infant Nasal CO2 Cannula	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D05V002MM			
4453 - NomoLine-O HH Adult Nasal/ Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
4459 - NomoLine-O LH Adult Nasal/ Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
4460 - NomoLine-O LH Pediatric Nasal/ Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
4636 - NomoLine-O LH Adult Nasal/ Oral CO2 Cannula 4m	Class IIa R020108		2023-05-10
4638 - NomoLine-O LH Adult Nasal/ Oral CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4639 - NomoLine-O LH Pediatric Nasal/ Oral CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4647 - NomoLine-O HH Pediatric Nasal/ Oral CO2 Cannula with O2	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D05V003MP			

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Product	Classification and EMDN	Intended use ¹	Date Added
4663 - NomoLine-O LH Adult Single Nasal Prong CO2 Cannula	Class IIa R020108		2023-05-10
4665 - NomoLine-O HH Adult Single Nasal Prong CO2 Cannula	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z3T5D05V004MR			
4451 - NomoLine-O HH Adult Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
4456 - NomoLine-O LH Adult Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
4457 - NomoLine-O LH Pediatric Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
4634 - NomoLine-O LH Adult Nasal CO2 Cannula with O2 4m	Class IIa R020108		2023-05-10
4645 - NomoLine-O HH Pediatric Nasal CO2 Cannula with O2	Class IIa R020108		2023-05-10
4934 - NomoLine-O HH Infant Nasal CO2 Cannula with O2, 4m, 25/Box	Class IIa R020108		2025-06-05
4969 - NomoLine-O HH Adult Nasal/Oral CO2 Cannula with O2, 4m, 25/box	Class IIa R020108		2025-06-05
Basic UDI-DI: 084399700000Z3T5D05V005MT			
4458 - NomoLine-O LH Adult Nasal/ Oral CO2 Cannula	Class IIa R020108		2023-05-10
4642 - NomoLine-O LH Pediatric Nasal/ Oral CO2 Cannula	Class IIa R020108		2023-05-10
Basic UDI-DI: 084399700000Z4T1B10V100HT			
3756 - O3 Sensor, rSO2, SpO2, Large Adhesive Sensor	Class IIb Z1203020406	The O3 Adult Sensor is intended for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors.	2024-10-02
4235 - O3 Sensor rSO2, SpO2, Pediatric Adhesive Sensor	Class IIb Z1203020406	The O3 Pediatric Sensor is intended for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors.	2024-10-02
4384 - O3 Regional Oximetry Sensor, Infant/Neonatal	Class IIb Z1203020406	The O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors in patients.	2024-10-02
Basic UDI-DI: 084399700000Z4T4B10V000KF			
4431 - O3 Regional Oximeter, Philips	Class IIb Z1203020406	The O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors in patients.	2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
4496 - O3 Regional Oximeter, D8 Connector, Masimo	Class IIb Z1203020406	The O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors in patients.	2025-03-06
9637 - O3 Regional Oximeter	Class IIb Z1203020406	The O3 Regional Oximeter System and accessories are intended for the use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors in patients in healthcare environments.	2025-03-06
Basic UDI-DI: 084399700000Z5T4B09V000P2			
4432 - SedLine Module, Philips	Class IIb Z12100302	The SedLine Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals.	2025-03-06
4497 - SedLine Module	Class IIb Z12100302	The SedLine Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals.	2025-03-06
9513 - SedLine (Module, Patient Cable)	Class IIb Z12100302	The SedLine Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals.	2025-03-06
9829 - Sedline module (v2.0)	Class IIb Z12100302	The SedLine Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals.	2025-03-06
Basic UDI-DI: 084399700000Z6T5A03V000MX			
4888 - Radius VSM Multi-functional Reusable Pod (ECG)	Class IIb Z1203020202	The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital, healthcare facilities, and home environments. The Radius VSM and accessories are intended for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth based respiration rate) physiological parameters.	2025-03-06
Basic UDI-DI: 084399700000Z7T4C01V000NM			
95059 - LiDCO Module Hemodynamic Monitor <i>LiDCO BIC</i>	Class IIb Z12050702	The LiDCO® Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients. The LiDCO® module should be used in conjunction with a patient monitor at all times. It digitises, analyses & transfers the hemodynamic parameters derived from the analogue signal obtained from a B.P. monitor (non invasive or invasive) to 3rd party connected monitor (Masimo Root) for display. In addition to arterial blood pressure parameters and cardiac output, the LiDCO Module calculates a number of derived parameters: Body Surface Area, Heart Rate Variation, Pulse Pressure Variation %, Stroke Volume Variation %, Cardiac Index, Stroke Volume, Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index, Oxygen Delivery/Index, Oxygen Consumption/Index, Heart Rate	2023-09-18

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Product	Classification and EMDN	Intended use ¹	Date Added
95060 - LiDCO Module Hemodynamic Monitor <i>LiDCO BIC</i>	Class IIb Z12050702	The LiDCO® Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients. The LiDCO® module should be used in conjunction with a patient monitor at all times. It digitises, analyses & transfers the hemodynamic parameters derived from the analogue signal obtained from a B.P. monitor (non invasive or invasive) to 3rd party connected monitor (Masimo Root) for display. In addition to arterial blood pressure parameters and cardiac output, the LiDCO Module calculates a number of derived parameters: Body Surface Area, Heart Rate Variation, Pulse Pressure Variation %, Stroke Volume Variation %, Cardiac Index, Stroke Volume , Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index, Oxygen Delivery/Index, Oxygen Consumption/Index, Heart Rate	2023-09-18
95098 - LiDCO Module Hemodynamic Monitor <i>LiDCO BIC</i>	Class IIb Z12050702	The LiDCO® Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients. The LiDCO® module should be used in conjunction with a patient monitor at all times. It digitises, analyses & transfers the hemodynamic parameters derived from the analogue signal obtained from a B.P. monitor (non invasive or invasive) to 3rd party connected monitor (Masimo Root) for display. In addition to arterial blood pressure parameters and cardiac output, the LiDCO Module calculates a number of derived parameters: Body Surface Area, Heart Rate Variation, Pulse Pressure Variation %, Stroke Volume Variation %, Cardiac Index, Stroke Volume , Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index, Oxygen Delivery/Index, Oxygen Consumption/Index, Heart Rate	2023-09-18
95099 - LiDCO Module Hemodynamic Monitor <i>LiDCO BIC</i>	Class IIb Z12050702	The LiDCO® Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients. The LiDCO® module should be used in conjunction with a patient monitor at all times. It digitises, analyses & transfers the hemodynamic parameters derived from the analogue signal obtained from a B.P. monitor (non invasive or invasive) to 3rd party connected monitor (Masimo Root) for display. In addition to arterial blood pressure parameters and cardiac output, the LiDCO Module calculates a number of derived parameters: Body Surface Area, Heart Rate Variation, Pulse Pressure Variation %, Stroke Volume Variation %, Cardiac Index, Stroke Volume , Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index, Oxygen Delivery/Index, Oxygen Consumption/Index, Heart Rate	2023-09-18
Basic UDI-DI: 084399700000Z9T1B12V100P2			
4776 - Radius T	Class IIa V0301010201		2025-03-06
4779 - Radius T° for Masimo SafetyNet	Class IIa V0301010201		2025-03-06

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Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 735004613000Z3T3D02V000UG			
3639 - EMMA Kit Capnograph mmHg	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring in mmHg)	2023-05-10
3678 - EMMA Kit Capnograph kPa	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring kPa)	2023-05-10
605100 - EMMA Kit Capnograph kPa	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring kPa)	2023-05-10
605102 - EMMA Kit Capnograph mmHg	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring mmHg)	2023-05-10
655100 - Radius PCG Kit Capnograph kPa	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring kPa)	2023-05-10
655102 - Radius PCG Kit Capnograph mmHg	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring mmHg)	2023-05-10
9961 - Radius PCG Kit Capnograph mmHg	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring mmHg)	2023-05-10
9962 - Radius PCG Kit Capnograph kPa	Class IIb Z1203020401	EMMA measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients. (Measuring kPa)	2023-05-10
Basic UDI-DI: 735004613000Z3T5D02V000VN			
100620 - Emma Airway Adapter Adult/ Pediatric	Class IIa R020302		2023-05-10
100660 - EMMA Airway Adapter Infant	Class IIa R020302		2023-05-10

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Product	Classification and EMDN	Intended use ¹	Date Added
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James Glaisher
Certification Authority, MDR
Intertek Medical Notified Body AB
Torshamnsgatan 43,
Box 1103, SE - 164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



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