



MASIMO INTERNATIONAL SARL  
Puits-Godet 10  
2000 Neuchâtel - SWITZERLAND

## LETTER OF AUTHORIZATION

September 13th , 2013

Dear Sir/Madam,

Masimo International SARL ("**Masimo**"), as the owner and producer of the products listed below, with its corporate headquarters at Puits-Godet 10, 2000, Neuchatel, Switzerland, hereby appoints "**Echipamed Plus SRL**" a company organized and existing under the laws of Republic of Moldova and with its business address at Str. Valea Trandafililor 24 B, of 80, Chisinau, 2001, Republic of Moldova ("**Echipamed Plus SRL**"), as an authorized distributor in the territory of Republic of Moldova on Masimo's behalf.

This appointment applies to the following products with all related accessories and attachments:

- LNOP® Sensors (Adhesive & Reusable) and Patient Cables Product Family
- LNOPv® Adhesive Sensor product family
- LNOP® MAC-1 Cables
- LNOP® Red Patient cables product family
- LNOP® Adapter Cables
- LNCS® Sensors (Adhesive & Reusable) and Patient Cables Product Family
- LNC™ Patient Cables (for use with Masimo SET Devices)
- LNCS® Adapter Cables
- LNCS® MAC cables
- M-LNCS™ Sensors (Adhesive, Specialty & Reusable) and Patient Cables Product Family
- Red Sensors
- Red™ Direct Connect Sensors (for use with Masimo Rainbow SET Devices)
- Direct Connect Sensors (for use with Masimo SET Devices)
- Rainbow® Sensors (Adhesive, Reusable and Disposable) and Patient Cables, Product family
- Rainbow® Direct Connect Sensors
- Masimo Sensor Accessories
- Masimo Sensor Sample pacs
- SpO2.com Sensors & cables product family,
- Masimo SET® Pulse Oximetry Devices (monitors)
- Masimo Rainbow SET™ Devices (monitors)
- Masimo SET Pulse Oximeters & Pulse CO-Oximeters and their accessories
- Handheld Pulse Oximeters & their accessories





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Page 2 of 2

- Masimo Rainbow SET™ Device Options (including the following Rainbow Application Parameters):

Total Hemoglobin (SpHb)  
Carboxyhemoglobin (SpCO)  
Methemoglobin (SpMet)  
PI Delta 3D Alarm  
DESAT index 3D Alarm  
Pleth Variability Index (PVI)

- SatShare® Cables
- PSN (Patient Safety Net)
- OEMs Monitor Upgrades and Compatible Devices

**Echipamed Plus SRL** is authorised to import, market, sell, commission and service the products and to participate in public and private tenders. This appointment is valid from the date first written above and terminates automatically if the Distribution Agreement ends for any reason.

Yours Sincerely,

*George Burridge  
Director, Finance  
Masimo International*



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Masimo Corporation

Main site: 52 Discovery, Irvine, California, 92618, United States

Additional sites are detailed in the attached appendix

has been registered by Intertek as conforming to the requirements of

## EN ISO 13485:2016

The management system is applicable to:

Design and development, manufacture, servicing and distribution of pulse oximeters and accessories (cables and sensors); respiratory monitors and accessories (cables and sensors); EEG monitors and accessories (cables and sensors); physiologic monitoring systems for blood pressure and body temperature; capnography monitors and accessories (sampling lines and cannulas); ECG monitors and accessories (ECG electrodes); patient monitoring devices (cables and sensors); gas monitoring devices and accessories (sampling lines and cannulas); and hemodynamic monitoring systems and accessories (cables) for the area of respiratory care and anesthesia.

Design and development, manufacture, installation, servicing and distribution of telemetric physiologic monitoring systems for the area of respiratory care and anesthesia.

Design and development, manufacture and distribution of regional oximeters and accessories (cables and sensors); blood pressure cuffs; compact multi-gas sensors; and percutaneous nerve stimulators for the area of respiratory care and anesthesia

Certificate Number:

0113397

Revision:

07

Initial Certification Date:

30 April 2021

Date of Certification Decision:

4 December 2024

Certificate Valid Date:

4 December 2024

Certificate Expiry Date:

10 May 2027



**Brian Mather**

Certification Authority, Intertek Medical  
Notified Body AB

Intertek Medical-Notified Body AB  
P.O. Box 1103, SE-164 22 Kista, Sweden





Masimo  
52 Discovery  
Irvine CA 92618

## EC DECLARATION OF CONFORMITY

**Manufacturer's Name:** Masimo Corporation  
**Business Address:** 52 Discovery, Irvine, CA 92618, USA  
**European Representative:** Medical Device Safety Service GmbH  
Schiffgraben 41, 30175 Hannover, Germany

**Product(s):** RAS Sensors  
DC rainbow SET Reusable Sensors  
DC SET Reusable Sensors  
LNCS SET Disposable Sensors  
LNCS SET Reusable Sensors  
M-LNCS rainbow SET Disposable Sensors  
M-LNCS rainbow SET Reusable Sensors  
M-LNCS SET Disposable Sensors  
M-LNCS SET Reusable Sensors  
Rad-G Reusable Sensors  
RD rainbow SET Disposable Sensors  
RD rainbow SET Reusable Sensors  
RD SET Disposable Sensors  
RD SET Reusable Sensors  
Red SET Reusable Sensors  
SpO2.COM Sensors  
(see Attachment for detailed product names)

**Classification:** Class IIb (per MDD Annex IX, Rule 10)

**Conformity Assessment Route:** MDD Annex II (excluding section 4)

**UMDNS and GMDN Code(s):** (see Attachment for codes and terms)

**Standards Applied:** Refer to Essential Requirements Checklist in TFA-1186, Harmonized Standards  
Applied in support of MDD and RoHS

We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of European Directive 93/42/EEC on Medical Devices (MDD), as amended, as well as of European Directive 2011/65/EU on Restriction of Hazardous Substances (RoHS). All supporting documentation is retained under the premises of the manufacturer.

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

**Notified Body:** TÜV SUD Product Services GmbH  
Ridlerstrasse 65, 80339 Munchen-Germany  
Identification no. 0123

**EC-Certificate:** G1 092076 0024 Rev. 00

**Signature:**

Linus Park  
VP, Regulatory  
Masimo Corporation

2022-05-24

Date





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### ATTACHMENT

| Product Family                  | Product Name                  | Part Number | UMDNS Code                           | GMDN Code                                  |
|---------------------------------|-------------------------------|-------------|--------------------------------------|--------------------------------------------|
| RAS Sensors                     | RAS-125c                      | 3456        | 13754<br>Stethoscopes,<br>Electronic | 13754<br>Electronic stethoscope            |
|                                 | RAS-125c                      | 3475        |                                      |                                            |
|                                 | RAS-125c                      | 3401        |                                      |                                            |
|                                 | RAS-125c                      | 3483        |                                      |                                            |
|                                 | RAS-45                        | 4171        |                                      |                                            |
|                                 | RAS-45 Inf/Neo                | 4425        |                                      |                                            |
|                                 | Radius VSM RAS-45             | 4828        |                                      |                                            |
| DC rainbow SET Reusable Sensors | rainbow DCI-dc3               | 2201        | 17594<br>Probes, Oximeter            | 47582<br>Pulse Co-oximeter probe, reusable |
|                                 | rainbow DCI-dc12              | 2202        |                                      |                                            |
|                                 | rainbow DC-3 SC 200           | 2646        |                                      |                                            |
|                                 | rainbow DCI-dc8               | 2407        |                                      |                                            |
| DC SET Reusable Sensors         | DCSC                          | 1396        | 17594<br>Probes, Oximeter            | 37808<br>Pulse oximeter probe, reusable    |
|                                 | DC-8                          | 2387        |                                      |                                            |
|                                 | DBI-dc3                       | 2651        |                                      |                                            |
|                                 | DBI-dc8                       | 2652        |                                      |                                            |
| LNCS SET Disposable Sensors     | LNCS Actx                     | 1859        | 17594<br>Probes, Oximeter            | 31658<br>Pulse oximeter probe, single-use  |
|                                 | LNCS Neo-L                    | 1862        |                                      |                                            |
|                                 | LNCS Pctx                     | 1860        |                                      |                                            |
|                                 | LNCS Inf-L                    | 1861        |                                      |                                            |
|                                 | LNCS NeoPt-L                  | 1901        |                                      |                                            |
|                                 | LNCS Neo                      | 2329        |                                      |                                            |
|                                 | LNCS Inf                      | 2328        |                                      |                                            |
|                                 | LNCS NeoPt                    | 2330        |                                      |                                            |
|                                 | LNCS Neo-3                    | 2320        |                                      |                                            |
|                                 | LNCS Actx-3                   | 2317        |                                      |                                            |
|                                 | LNCS Pctx-3                   | 2318        |                                      |                                            |
|                                 | LNCS NeoPt-3                  | 2321        |                                      |                                            |
|                                 | LNCS Inf-3                    | 2319        |                                      |                                            |
|                                 | LNCS Trauma Adult             | 2411        |                                      |                                            |
|                                 | LNCS Newborn Neo              | 2412        |                                      |                                            |
|                                 | LNCS NeoPt-500                | 2331        |                                      |                                            |
|                                 | LNCS Newborn Infant/Pediatric | 2413        |                                      |                                            |
|                                 | LNCS Actx-3                   | 2601        |                                      |                                            |
|                                 | LNCS Pctx-3                   | 2602        |                                      |                                            |
|                                 | LNCS Inf-3                    | 2603        |                                      |                                            |
|                                 | LNCS Neo-3                    | 2604        |                                      |                                            |
|                                 | LNCS NeoPt-3                  | 2605        |                                      |                                            |
|                                 | LNCS NeoPt-500                | 2606        |                                      |                                            |
|                                 | LNCS EI                       | 2918        |                                      |                                            |
|                                 | LNCS Red TFA-1                | 3857        |                                      |                                            |
|                                 | LNCS TFA-1                    | 3858        |                                      |                                            |
|                                 | LNCS Actx                     | 4714        |                                      |                                            |
|                                 | LNCS Pctx/Inf/Neo Sensor Kit  | 4715        |                                      |                                            |





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52 Discovery  
Irvine CA 92618

| Product Family                        | Product Name                   | Part Number | UMDNS Code                | GMDN Code                                    |
|---------------------------------------|--------------------------------|-------------|---------------------------|----------------------------------------------|
| LNCS SET Reusable Sensors             | LNCS TC-I                      | 1895        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe, reusable      |
|                                       | LNCS DCI                       | 1863        |                           |                                              |
|                                       | LNCS DCI-P                     | 1864        |                           |                                              |
|                                       | LNCS TF-I                      | 1896        |                           |                                              |
|                                       | LNCS YI                        | 2258        |                           |                                              |
|                                       | LNCS DBI                       | 2653        |                           |                                              |
|                                       | LNCS DCIv                      | 2924        |                           |                                              |
|                                       | M-LNCS DCI                     | 2501        |                           |                                              |
| M-LNCS rainbow SET Disposable Sensors | R25-L                          | 2219        | 17594<br>Probes, Oximeter | 47581<br>Pulse Co-oximeter probe, single-use |
|                                       | R20-L                          | 2220        |                           |                                              |
|                                       | R20                            | 2222        |                           |                                              |
|                                       | R 25                           | 2221        |                           |                                              |
|                                       | R1 25L                         | 2414        |                           |                                              |
|                                       | R1 20L                         | 2415        |                           |                                              |
|                                       | R1 25                          | 3792        |                           |                                              |
|                                       | R1 20                          | 3793        |                           |                                              |
| M-LNCS rainbow SET Reusable Sensors   | rainbow DCIP-dc3               | 2069        | 17594<br>Probes, Oximeter | 47582<br>Pulse Co-oximeter probe, reusable   |
|                                       | rainbow DCIP-dc12              | 2070        |                           |                                              |
|                                       | rainbow DCIP-dc8               | 2640        |                           |                                              |
|                                       | rainbow DCP-3 SC 200           | 2647        |                           |                                              |
|                                       | rainbow DCI                    | 2696        |                           |                                              |
|                                       | rainbow DCIP                   | 2697        |                           |                                              |
|                                       | rainbow DCI SC 200             | 3418        |                           |                                              |
|                                       | rainbow DCIP SC 200            | 3419        |                           |                                              |
|                                       | rainbow DCI SC 400             | 3420        |                           |                                              |
|                                       | rainbow DCIP SC 400            | 3421        |                           |                                              |
|                                       | rainbow DCI SC 1000            | 3647        |                           |                                              |
|                                       | rainbow DCIP SC 1000           | 3648        |                           |                                              |
|                                       | rainbow DCI-6                  | 3657        |                           |                                              |
|                                       | rainbow DCIP-6                 | 3658        |                           |                                              |
|                                       | rainbow DCI-mini SC 200        | 3797        |                           |                                              |
|                                       | rainbow DCI-mini SC 400        | 3798        |                           |                                              |
|                                       | rainbow DCI-mini SC 1000       | 3799        |                           |                                              |
|                                       | rainbow Super DCI-mini SC 200  | 4309        |                           |                                              |
|                                       | rainbow Super DCI-mini SC 400  | 4310        |                           |                                              |
|                                       | rainbow Super DCI-mini SC 1000 | 4311        |                           |                                              |
| M-LNCS SET Disposable Sensors         | M-LNCS Amtx                    | 2508        | 17594<br>Probes, Oximeter | 31658<br>Pulse oximeter probe, single-use    |
|                                       | M-LNCS Amtx-3                  | 2509        |                           |                                              |
|                                       | M-LNCS Pmtx                    | 2510        |                           |                                              |
|                                       | M-LNCS Pmtx-3                  | 2511        |                           |                                              |
|                                       | M-LNCS Inf                     | 2512        |                           |                                              |
|                                       | M-LNCS Inf-3                   | 2513        |                           |                                              |
|                                       | M-LNCS Neo                     | 2514        |                           |                                              |





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Irvine CA 92618

| Product Family                    | Product Name                         | Part Number | UMDNS Code                | GMDN Code                                    |
|-----------------------------------|--------------------------------------|-------------|---------------------------|----------------------------------------------|
|                                   | M-LNCS Neo-3                         | 2515        |                           |                                              |
|                                   | M-LNCS NeoPt                         | 2516        |                           |                                              |
|                                   | M-LNCS NeoPt-3                       | 2517        |                           |                                              |
|                                   | M-LNCS NeoPt-500                     | 2518        |                           |                                              |
|                                   | M-LNCS EI                            | 2919        |                           |                                              |
|                                   | M-LNCS Neo-L                         | 3668        |                           |                                              |
|                                   | M-LNCS NeoPt-L                       | 3669        |                           |                                              |
|                                   | M-LNCS Inf-L                         | 3670        |                           |                                              |
| M-LNCS SET Reusable Sensors       | M-LNCS TFA-I                         | 3856        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe, reusable      |
|                                   | M-LNCS DCI-P                         | 2502        |                           |                                              |
|                                   | M-LNCS TC-I                          | 2503        |                           |                                              |
|                                   | M-LNCS TF-I                          | 2504        |                           |                                              |
|                                   | M-LNCS YI                            | 2505        |                           |                                              |
| Rad-G Reusable Sensors            | M-LNCS DBI                           | 2507        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe, reusable      |
|                                   | Rad-G Sensor                         | 4325        |                           |                                              |
|                                   | Rad-G YI                             | 4653        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe, reusable      |
|                                   |                                      |             |                           |                                              |
| RD rainbow SET Disposable Sensors | RD rainbow SET-2 Adt                 | 4026        | 17594<br>Probes, Oximeter | 47581<br>Pulse Co-oximeter probe, single-use |
|                                   | RD rainbow SET-2 Pdt                 | 4027        |                           |                                              |
|                                   | RD rainbow SET-2 Inf                 | 4028        |                           |                                              |
|                                   | RD rainbow SET-2 Neo                 | 4029        |                           |                                              |
|                                   | RD rainbow Lite SET-1 Adt            | 4042        |                           |                                              |
|                                   | RD rainbow Lite SET-1 Pdt            | 4043        |                           |                                              |
|                                   | RD rainbow Lite SET-1 Inf            | 4044        |                           |                                              |
|                                   | RD rainbow Lite SET-1 Neo            | 4045        |                           |                                              |
|                                   | RD rainbow Adt 8λ SpCO               | 4034        |                           |                                              |
|                                   | RD rainbow Pdt 8λ SpCO               | 4035        |                           |                                              |
|                                   | RD rainbow Inf 8λ SpCO               | 4036        |                           |                                              |
|                                   | RD rainbow Neo 8λ SpCO               | 4037        |                           |                                              |
|                                   | RD rainbow Adt 12λ SpHb SpCO         | 4038        |                           |                                              |
|                                   | RD rainbow Pdt 12λ SpHb SpCO         | 4039        |                           |                                              |
|                                   | RD rainbow Inf 12λ SpHb SpCO         | 4040        |                           |                                              |
|                                   | RD rainbow Neo 12λ SpHb SpCO         | 4041        |                           |                                              |
| RD rainbow SET Reusable Sensors   | LNCS-II rainbow DCI 8λ SpCO          | 4067        | 17594<br>Probes, Oximeter | 47582<br>Pulse Co-oximeter probe, reusable   |
|                                   | LNCS-II rainbow DCIP 8λ SpCO         | 4068        |                           |                                              |
|                                   | LNCS-II rainbow DCI-6 8λ SpCO        | 4069        |                           |                                              |
|                                   | LNCS-II rainbow DCIP-6 8λ SpCO       | 4070        |                           |                                              |
|                                   | LNCS-II rainbow DCI 8λ SpHb SC 200   | 4058        |                           |                                              |
|                                   | LNCS-II rainbow DCIP 8λ SpHb SC 200  | 4061        |                           |                                              |
|                                   | LNCS-II rainbow DCI 8λ SpHb SC 400   | 4059        |                           |                                              |
|                                   | LNCS-II rainbow DCIP 8λ SpHb SC 400  | 4062        |                           |                                              |
|                                   | LNCS-II rainbow DCI 8λ SpHb SC 1000  | 4060        |                           |                                              |
|                                   | LNCS-II rainbow DCIP 8λ SpHb SC 1000 | 4063        |                           |                                              |





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Irvine CA 92618

| Product Family            | Product Name                    | Part Number | UMDNS Code                | GMDN Code                                    |
|---------------------------|---------------------------------|-------------|---------------------------|----------------------------------------------|
| RD SET Disposable Sensors | RD SET Adt                      | 4000        | 17594<br>Probes, Oximeter | 31658<br>Pulse oximeter probe,<br>single-use |
|                           | RD SET Pdt                      | 4001        |                           |                                              |
|                           | RD SET Inf                      | 4002        |                           |                                              |
|                           | RD SET Neo                      | 4003        |                           |                                              |
|                           | RD SET NeoPt                    | 4004        |                           |                                              |
|                           | RD SET NeoPt-500                | 4005        |                           |                                              |
|                           | RD SET Trauma                   | 4011        |                           |                                              |
|                           | RD SET Newborn Infant/Pediatric | 4012        |                           |                                              |
|                           | RD SET Newborn Neonatal         | 4013        |                           |                                              |
|                           | RD SET Blue                     | 4014        |                           |                                              |
|                           | RD SET E1                       | 4015        |                           |                                              |
|                           | RD SET TFA-1                    | 4016        |                           |                                              |
|                           | RD SET Adt CS-2                 | 4470        |                           |                                              |
|                           | RD SET Pdt CS-2                 | 4471        |                           |                                              |
|                           | RD SET Inf CS-2                 | 4472        |                           |                                              |
|                           | RD SET Neo CS-2                 | 4473        |                           |                                              |
|                           | RD SET NeoPt CS-2               | 4474        |                           |                                              |
|                           | RD SET Adt CS-3                 | 4475        |                           |                                              |
|                           | RD SET Pdt CS-3                 | 4476        |                           |                                              |
|                           | RD SET Inf CS-3                 | 4477        |                           |                                              |
|                           | RD SET Neo CS-3                 | 4478        |                           |                                              |
|                           | RD SET NeoPt CS-3               | 4479        |                           |                                              |
|                           | RD SET Adt CS-1                 | 4615        |                           |                                              |
|                           | RD SET Neo CS-1                 | 4886        |                           |                                              |
| RD SET Reusable Sensors   | RD SET DCI                      | 4050        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe,<br>reusable   |
|                           | RD SET DCI-P                    | 4051        |                           |                                              |
|                           | RD SET TC-I                     | 4053        |                           |                                              |
|                           | RD SET YI                       | 4054        |                           |                                              |
|                           | RD SET TF-I                     | 4055        |                           |                                              |
|                           | RD SET DBI                      | 4052        |                           |                                              |
| Red SET Reusable Sensors  | Red DCI-dc3                     | 2053        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe,<br>reusable   |
|                           | Red DCI-dc12                    | 2054        |                           |                                              |
|                           | Red DCIP-dc12                   | 2257        |                           |                                              |
|                           | Red DCIP-dc3                    | 2256        |                           |                                              |
|                           | Red DBI-dc3                     | 2643        |                           |                                              |
|                           | Red DBI-dc8                     | 2644        |                           |                                              |
| SpO2.COM Sensors          | SpO2.com A                      | 1774        | 17594<br>Probes, Oximeter | 31658<br>Pulse oximeter probe,<br>single-use |
|                           | SpO2.com P                      | 1775        |                           |                                              |
|                           | SpO2.com N                      | 1776        |                           |                                              |
|                           | SpO2.com I                      | 1777        |                           |                                              |
|                           | SpO2.com RS-I                   | 1778        | 17594<br>Probes, Oximeter | 37808<br>Pulse oximeter probe,<br>reusable   |

