



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





- 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*





Product Service

Certificate

No. Q5 092076 0012 Rev. 00

Holder of Certificate: **Masimo Corporation**

52 Discovery
Irvine CA 92618
USA

Certification Mark:



Scope of Certificate:

- Design and Development, Production and Distribution of Pulse Oximeters and Accessories (Cables and Sensors), Regional Oximeters and Accessories (Cables and Sensors)
- Design and Development, Production and Distribution and Installation of Telemetric Physiologic Monitoring System.
- Design and Development, Production and Distribution of Respiratory Monitors and Accessories (Cables and Sensors).
- Design and Development, Production and Distribution of EEG Monitors and Accessories (Cables and Sensors).
- Design and Development, Production and Distribution of Physiologic Monitoring Systems for Blood Pressure and Body Temperature.
- Design and Development, Production and Distribution of Capnography Monitors and Accessories (Sampling Lines and Cannulas).

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72148776

Valid from: 2019-07-01

Valid until: 2022-01-02

Date, 2019-07-01

[Handwritten Signature]

Stefan Preiß
Head of Certification/Notified Body





Certificate

No. Q5 092076 0012 Rev. 00

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): Masimo Corporation
 52 Discovery, Irvine CA 92618, USA

Masimo Corporation
 15776 Laguna Canyon Road, Irvine CA 92618, USA

Masimo Corporation
 9600 Jeronimo, Irvine CA 92618, USA

Industrial Vallera de Mexicali, S.A de C.V
 Calzada del Oro # 2001, 21600 Parque Ind. Palaco Mexicali BC,
 MEXICO

Industrial Vallera de Mexicali S.A. de C.V.
 Calle José López Portillo, 104-A, Parque Industrial, Código Postal,
 83455 San Luis Rio Colorado, Sonora, MEXICO

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 92076 008

Manufacturer: Masimo Corporation

52 Discovery
Irvine CA 92618
USA

EC-Representative: Medical Device Safety Service GmbH

Schiffgraben 41
30175 Hannover
GERMANY



Product Category(ies):

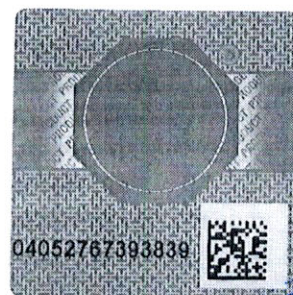
Pulse Oximeters and Accessories (Cables and Sensors). Telemetric Physiologic Monitoring System, Respiratory Monitors and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Regional Oximeters and Accessories (Cables and Sensors), Physiologic Monitoring Systems (for Blood Pressure and Body Temperature), Capnography Monitors and Accessories (Sampling Lines and Cannulas)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72137695

Valid from: 2018-07-16

Valid until: 2023-07-15



Date, 2018-07-06

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany





Product Service

EC Certificate Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 92076 008

Facility(ies):

Masimo Corporation
52 Discovery, Irvine CA 92618, USA

Masimo Corporation
40 Parker, Irvine CA 92618, USA

Masimo Corporation
9600 Jeronimo, Irvine CA 92618, USA

Industrial Vallera de Mexicali, S.A de C.V
Calzada del Oro # 2001, 21600 Parque Ind. Palaco Mexicali BC,
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