ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Iurchevici Valeriu
Date: 2025.05.05 14:07:56 EEST
Reason: MoldSign Signature
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MOLDOVA EUROPEANĂ

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

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Date, 2018-07-06

Stefan Preiß

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

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

A1 / 04.11

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TÜV SÜD 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, MEXICO

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

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

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

TÜV®

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Masimo
52 Discovery
Irvine, CA 92618

June 19, 2023

Re: Masimo's Declaration Confirming Conditions for EU MDR Extension per Regulation 2023/607 are Fulfilled

To whom it may concern:

Masimo declares its legacy devices are covered by the transitional period stated in Regulation (EU) 2023/607, amending Regulations (EU) 2017/745. Masimo's certificate is issued by TÜV SÜD in accordance with Council Directives 93/42/EEC, was still valid on 26 May 2021, and has not been withdrawn afterwards. Masimo's EC Certificate remains valid after the expiry date of the certificate until December 31, 2028 set by EU MDR Amendment 2023/607. Masimo has fulfilled all conditions required to continue to place medical devices in the market.

Legal Manufacturer:
Masimo Corporation
52 Discovery, Irvine, CA, 92618, United States of America
SRN: US-MF-000010641

European Authorized Representative (EAR):
Medical Device Safety Services (MDSS)
Schiffgraben 41, 30175 Hannover, Germany
SRN: DE-AR-000005430

Notified Body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany
NB ID: 0123

Certificate Number: G1 092076 0024
End Date of Transitional Period: 31 December 2028

Device Classification: lla, llb
Devices Covered by Extension: 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), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System.

Conditions laid down in Article 120(3c) as amended by regulation 2023/607.

a. Masimo medical devices continue to comply with Council Directive 93/42/EEC;
b. There are no significant changes in the design and intended purpose of Masimo's medical devices;
c. Masimo medical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
d. Masimo Corporation has put in place a quality management system in accordance with Article 10(9);
e. Masimo has lodged a formal application with TÜV SÜD covering all Masimo medical devices. Masimo and TÜV SÜD have signed a written agreement in accordance with Regulation 2023/607.

Sincerely,

Mathew Jimenez
Senior Vice President, Worldwide Quality & Compliance
Email: mjimenez@masimo.com
Phone: +1 949-297-7558