



Product Service

# Certificate

No. Q5 092076 0026 Rev. 01

**Holder of Certificate:** **Masimo Corporation**  
 52 Discovery  
 Irvine CA 92618  
 USA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Service 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).

Design and Development, Production, Distribution and Installation of Telemetric Physiologic Monitoring System.

- Design and Development, Production and Distribution of:
- ECG Monitors and Accessories (ECG Electrodes),
  - Patient Position Monitoring System,
  - Regional Oximeters and Accessories (Cables and Sensors).

Design and Development, Production, and Distribution of Blood Pressure Cuffs.

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5\\_092076\\_0026\\_Rev.\\_01](http://www.tuvsud.com/ps-cert?q=cert:Q5_092076_0026_Rev._01)

**Report No.:** 72180133

**Valid from:** 2022-12-07

**Valid until:** 2024-12-20

**Date,** 2022-12-07

Christoph Dicks  
 Head of Certification/Notified Body







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**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

Design and Development of: 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, and Blood Pressure Cuffs.

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

Production of Components for Pulse Oximeters and Accessories (Cables and Sensors) and Regional Oximeters and Accessories (Cables and Sensors). Receiving, Incoming Inspection and Storage of Raw Materials. Installation of Telemetric Physiologic Monitoring System.

**Masimo Corporation**  
 9600 Jeronimo, Irvine CA 92618, USA

Production and Distribution of Pulse Oximeters and Accessories (Cables and Sensors). Distribution of: 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, and Blood Pressure Cuffs.

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

Production and Service of: Pulse Oximeters and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Physiologic Monitoring Systems for Blood Pressure and Body Temperature, Respiratory Monitors and Accessories (Cables and Sensors), Capnography Monitors and Accessories (Sampling Lines and Cannulas).





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Production of: ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System, and Regional Oximeters and Accessories (Cables and Sensors) and Telemetric Physiologic Monitoring System.

**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

Production of Pulse Oximeter Sensors.

**Industrial Vallera de Mexicali S.A. de C.V.**

Carretera Mexicali-Algodones # 4798 Int., 4-1, Col. Diez Division Dos, Baja California, 21395 Mexicali, MEXICO

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

Distribution of: Pulse Oximeters and Accessories, Telemetric Physiologic Monitoring System, EEG Monitors and Accessories (Cables and Sensors), Physiologic Monitoring Systems for Blood Pressure and Body Temperature, Respiratory Monitors and Accessories (Cables and Sensors), Capnography Monitors and Accessories (Sampling Lines and Cannulas), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System and Blood Pressure Cuffs.

**Masimo Corporation**

15750 Alton Parkway, Irvine CA 92618, USA

Regulatory, CAPA, Complaints and Internal Audit.

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