



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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 092076 0024 Rev. 00**

**Manufacturer:**

**Masimo Corporation**

52 Discovery  
Irvine CA 92618  
USA

**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), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System.

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. 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:G10920760024Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G10920760024Rev.00)

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**Date,** 2021-03-29

Christoph Dicks  
Head of Certification/Notified Body