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

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

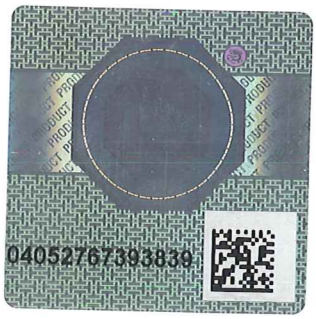
EC-Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
GERMANY

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

TÜV®

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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