



MASIMO CORPORATION  
Forty Parker  
Irvine, CA 92618

## EC DECLARATION OF CONFORMITY

**Manufacturer's Name:** Masimo Corporation

**Business Address:** 40 Parker  
Irvine, CA 92618  
USA

**European Representative:** Medical Device Safety Service GmbH  
Schiffgraben 41  
D-30175 Hannover, Germany

**Product(s):** Masimo SET Pulse Oximeter and Accessories:  
Radical, Rad 9, Rad 5, Rad 5v, Rad 8, Intellivue Module

Masimo SET Pulse Oximeter Sensors:  
LNOP, LNCS, SpO2.com, M-LNCS, Red (Reusable & Single Use/ Disposable/  
Adhesive)

Masimo SET Pulse Oximeter Cables:  
LNOP, LNCS, SpO2.com, M-LNCS, Red Patient/ Adapter Cables;  
Satshare Cables; Flex Instrument Cables

The Masimo Signal Extraction Technology (SET) in the above Masimo devices (instruments, sensors, and cables) has the capacity to provide arterial hemoglobin saturation (SpO2) and pulse rate measurements/ parameters.

**Classification:** Class IIb Pulse Oximeter and Sensors (per Annex IX, Rule 10); Class I for Cables (per Annex IX, Rule 1)

**Conformity Assessment Route:** Annex II section 3 (Class IIb products); Annex VII (Class I products)

**UMDNS Code(s) and Term(s):** 17148, Oximeter, Pulse  
17594, Probes, Oximeter  
16316, Cable/lead, Other  
15212, Clamps, Other

**GMDN Code(s) and Term(s):** 17148, Pulse Oximeter, Line-Powered  
45607, Pulse Oximeter, Battery-Powered  
37808, Probes, Pulse Oximeter, Reusable  
31658, Probes, Pulse Oximeter, Single Use  
47487, Medical Device Electrical Cable, General-Purpose  
36554, Patient Monitoring System Module, Pulse Oximetry

We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices, respectively, as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

**Standards Applied:** EN ISO 13485:2003, ISO 9919:2005, IEC/ EN 60601-1:1995, IEC/EN 60601-1-2:2001/A1:2004/ EN 60601-1-2:2001/A1:2006, IEC/ EN 62304:2006

**Notified Body:** TUV SUD Product Services GmbH  
Ridlerstrasse 65  
80339 Munchen, Germany  
Identification no. 0123

**(EC) Certificate:** G1 10 02 31548 018

**Place, Date of Issue:** Masimo Corp. Irvine, CA; August 26, 2010

**Signature:**

  
Anil Bhalani  
Director, Regulatory Affairs