



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