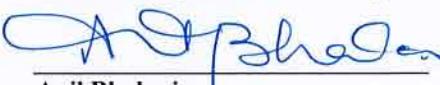




MASIMO CORPORATION
Forty Parker
Irvine, CA 92618

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