



Masimo
52 Discovery
Irvine CA 92618

EC DECLARATION OF CONFORMITY

Manufacturer's Name: Masimo Corporation

Business Address: 52 Discovery, Irvine, CA 92618, USA

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

Products: Masimo Instruments and Systems:

- Pulse Oximeters
- Telemetric Physiologic Monitoring System
- Respiratory Monitors
- EEG Monitors
- Regional Oximeters
- Physiologic Monitoring Systems

(see Attachment)

Classification: Class IIb (per Annex IX, Rule 10)

Conformity Assessment Route: Annex II (excluding section 4) of MDD

UMDNS Code(s) and Term(s): (see Attachment)

GMDN Code(s) and Term(s): (see Attachment)

Standards Applied: Refer to Essential Requirements Checklist of the Technical File or TFA-1186, Standards and Regulations for Masimo Products

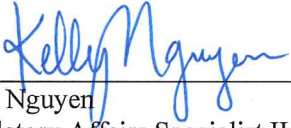
We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the European Council Directive 93/42/EEC for Medical Devices (MDD), as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2012.

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

EC-Certificate: G1 17 03 92076 001

Signature:



Kelly Nguyen
Regulatory Affairs Specialist II
Masimo Corporation, Irvine

Date

