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 — 2/8/18

Kelly Nguyen
Regulatory Affairs Specialist II
Masimo Corporation, Irvine

Date