

EC Declaration of Conformity

We Masimo Corporation located at 40 Parker, Irvine, CA 92618 USA and Calzada del Oro # 2001 Int. 5, 21600 Parque Ind. Palaco Mexicali BC, Mexico declare with sole responsibility, that our medical devices:

Masimo SET Rad 5/5v Pulse Oximeters and Accessories
(UMDNS code 17-148)

meet the provisions of Council Directive 93/42/EEC (MDD) which apply to them.

The obligation as laid down in Annex II of MDD 93/42/EEC are fulfilled.

Annex II certificate issued by: TÜV Product Service
Certificate No: G1 04 06 31548 009

In addition they meet (where applicable) the following:

DIN EN ISO 10993 Part 5

IEC 60601-1-1

IEC 60601 1-2

DIN 865-1997

ISO-13485

ISO-9919 - 1992

We hereby appoint MDSS, Burckhardstrasse 1, D - 30163 Hannover, Germany to act as European Authorized Representative as defined in Article 1(j) of the Medical Device Directive 93/42/EEC.

Irvine, CA 92618

Place and date of Issue



James J. Cronin

Vice President Regulatory Affairs/Quality Assurance