

Declaration of Conformity

Date: 21 July 2014

Manufacturer/Place of Declaration: Nonin Medical, Inc.
Address: 13700 1st Avenue North
Plymouth, MN 55441-5443 USA

Model Numbers and Product Designations: 8500, 8500M
Pulse Oximeter Systems

Device Category(ies): Oximeter, pulse

GMDN Number(s): 17148

Date Added: August 1995

We herewith declare that the above mentioned pulse oximeter and NIBP monitoring system is classified as Class IIb (using rule 10) and complies with Annex II, section 3 of the Directive No. 93/42/EEC on medical devices, as amended (2007/47/EC), Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, (RoHS) and all applicable clauses of ISO 80601-2-61:2011, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.*

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Notified Body: TÜV SÜD Product Service GmbH
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EC Certificate Number: G1 13 09 24497 023
Number CE0123

Signature: 
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