

Declaration of Conformity

Date: 21 July 2014

Manufacturer/Place of Declaration: Nonin

Address:

Nonin Medical, Inc.

13700 1st Avenue North

Plymouth, MN 55441-5443 USA

Model Numbers and

9600

Product Designations:

Avant® Pulse Oximeter System

Device Category(ies):

Oximeter, pulse

GMDN Number(s):

17148

Date Added:

November 2002

We herewith declare that the above mentioned pulse oximeter 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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

Ridlerstrasse 65 D-80339 München

Germany

EC Certificate Number:

G1 13 09 24497 023

Number

CE0123

Signature:

Kim E Avoc

Name:

Senior Regulatory Affairs Specialist

Title:

Authorized EC Representative:

Medical Product Service (MPS) GmbH

Borngasse 20

35619 Braunfels, Germany