

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:** 8000JFW
8001JFW
8008JFW

Device Category(ies): Adhesive Strips

GMDN Number(s): 10026

Release to Distribution Date: March 1999

We herewith declare that the above mentioned FlexiWrap® Single Use Sensor Wraps are classified as Class I (using rule 1) 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Signature:



Name:

Kim E. Aves

Title:

Senior Regulatory Affairs Specialist