ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# EC Certificate

## Full Quality Assurance System

**Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)**
**(Devices in Class IIa, IIb or III)**

**No. G1 13 09 24497 023**

**Manufacturer:**

**NONIN MEDICAL, INC.**
13700 1st Avenue North
Plymouth MN 55441-5443
USA

**EC-Representative:**

**MPS Medical Product Service GmbH**
Borngasse 20
35619 Braunfels
GERMANY

**Product Category(ies):**

**Oximeters, Pulse Oximeters, Cerebral Oximeters Breathing Monitors, Non-Invasive Blood Pressure Monitors, ECG Monitors and Non-Sterile Sensors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** DM1203078

**Valid from:** 2013-12-02
**Valid until:** 2018-12-01

**Date,** 2013-10-23

Hans-Heiner Junker

512810

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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## No. G1 13 09 24497 023

**Facility(ies):**

NONIN MEDICAL, INC.
13700 1st Avenue North, Plymouth MN 55441-5443, USA



TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany