ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 024497 0030 Rev. 00

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.: 72143491

Valid from: 2018-12-11
Valid until: 2023-12-01

Date, 2018-12-11

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

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

Nonin Medical Inc.
13705 1st Ave., Plymouth MN 55441, USA

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