



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 18 03 84065 005

**Manufacturer:** **Nuova GmbH**  
Lübecker Str. 17  
23909 Ratzeburg  
GERMANY



**Facility(ies):** Nuova GmbH  
Lübecker Str. 17, 23909 Ratzeburg, GERMANY

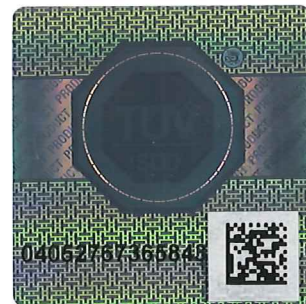
**Product Category(ies):** **Oxygen sensors**

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.:** 713129331

**Valid from:** 2018-06-18

**Valid until:** 2023-06-17



**Date,** 2018-04-18

Stefan Preiß

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

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Product Service

# CERTIFICATE

No. Q1N 16 04 84065 003

**Holder of Certificate:** **Nuova GmbH**  
 Lübecker Str. 17  
 23909 Ratzeburg  
 GERMANY

**Facility(ies):** Nuova GmbH  
 Lübecker Str. 17, 23909 Ratzeburg, GERMANY



**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of oxygen sensors, pulse oximetry sensors, blood warmer and breathing tubes**

**Applied Standard(s):** EN ISO 13485:2012 + AC:2012  
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
 DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713081659

**Valid from:** 2016-06-18  
**Valid until:** 2019-06-17



**Date,** 2016-06-15

*S. Preis*  
 Stefan Preis

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**E-75/9** (new release)

- Connector: 3.5 phone jack
- Measuring range 0-100% O<sub>2</sub>
- Output signal: 10-13,5 mV
- Response time: 13 seconds
- Warranty: 22 months
- Storage: up to 6 months with flow diverter