



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

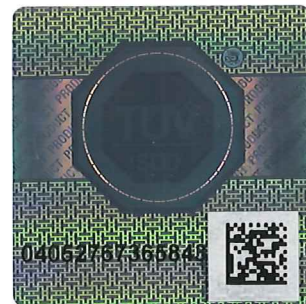
**Product Category(ies):** **Oxygen sensors**

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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# CERTIFICATE



## EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

**IT Dr. Gambert GmbH**

**Scope of certification:**

Design and development, manufacture and distribution of electro-chemical gas sensors for medical equipment

**Certified location:**

Hinter dem Chor 21, 23966 Wismar, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50403-Z6-00.

This certificate is valid from 2018-09-17 to 2021-09-16

Registration No.: 50403-14-00

  
Ruth Delbeck-Bayer



DEKRA Certification GmbH Stuttgart; 2018-08-31



Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00

E



## **E-17/A2**

- Connector: 3-pin Molex
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8–12.5 mV
- Response time: < 15 seconds
- Warranty: 16 months
- Storage: up to 6 months

E



## E-15/4

- Connector: modular jack
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8–12 mV
- Response time: < 16 seconds
- Warranty: 16 months
- Storage: up to 6 months

E



## E-17/A4

- Connector: 3-pin Molex
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 11-14 mV
- Response time: < 12 seconds
- Warranty: 12 months
- Storage: up to 3 months

E



## E-15/2

- Connector: 3 contact rings
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 14.–20 mV
- Response time: < 12 seconds
- Warranty: 15 months
- Storage: up to 6 months

E



## E-77/0S

- Connector: RJ11 modular jack
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 9-13 mV
- Response time: < 15 seconds
- Warranty: 16 months
- Storage: up to 6 months