E-77/0S

- Connector: RJ11 modular jack
- Measuring range: 0-100% O_2
- Output signal: 9-13 mV
- Response time: < 15 seconds
- Warranty: 16 months
- Storage: up to 6 months

E

E-17/M

- Connector: 3-pin Molex
- Measuring range: 0-100% O_2
- Output signal: 12.5-16.5 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months

Product Service

E C   C e r t i f i c a t e

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):

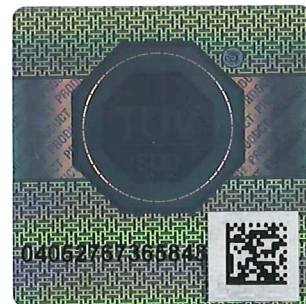Nuova GmbH
Lübecker Str. 17, 23909 Ratzeburg, GERMANY

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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A1 / 04.11

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

TÜV®

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

04052768777294

Date,   2016-06-15

Stefan Preiß

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