E E-09/0 Connector: 3-pin wired Molex Measuring range: 0- 100% O2 Output signal: 9.5–14 mV Response time: < 18 seconds Warranty: 16 months Storage: up to 6 months	E Fertive Connector: AMP350777- 1 2 way mating lock Measuring Range: 0- 100% O2 Output signal: 8.5- 12.5mV Response time: < 17 seconds Warranty: 16 months Storage: up to 6 months	<ul> <li>Final provide the second state of the</li></ul>	<ul> <li>First and the second second</li></ul>
E E E-15/0	E E E-15/2	E F15/4	E F-15/5
<ul> <li>Connector: 3 contact rings gold plated</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 14–20 mV</li> <li>Response time:&lt; 17 seconds</li> <li>Warranty: 16 months</li> </ul>	<ul> <li>Connector: 3 contact rings</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 14.–20 mV</li> <li>Response time: &lt; 12 seconds</li> <li>Warranty: 15 months</li> </ul>	<ul> <li>Connector: modular jack</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 8–12 mV</li> <li>Response time: &lt; 16 seconds</li> <li>Warranty: 16 months</li> </ul>	<ul> <li>Connector: 3.5 mm mono jack</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 8–12 mV</li> <li>Response time: &lt; 16 seconds</li> <li>Warranty: 16 months</li> </ul>

• Storage: up to 6 months	• Storage: up to 6 months	• Storage: up to 6 months	• Storage: up to 6 months
E	E	E	E
E-15/5M	E-16/0	E-16/HTT	E-17/A2
<ul> <li>specification as E-15/5 however different housing to fit for Mindray WATO</li> </ul>	<ul> <li>Connector: 3-pin Molex</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 9.5-16 mV</li> <li>Response time: &lt; 12 seconds</li> <li>Warranty: 16 months</li> <li>Storage: up to 6 months</li> </ul>	<ul> <li>Connector: 3-pin Molex</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>9.5-16 mV</li> <li>Response time: 12 s at flow &gt;2l/min</li> <li>Warranty: 12 months</li> <li>Storage: up to 6 months</li> </ul>	<ul> <li>Connector: 3-pin Molex</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 8–12.5 mV</li> <li>Response time: &lt; 15 seconds</li> <li>Warranty: 16 months</li> <li>Storage: up to 6 months</li> </ul>
E E-17/A2A	E E-17/A2MH3	E E-17/A4	E E-17/J
<ul> <li>Connector: 3 pin Molex</li> <li>Measuring Range: 0- 100% O2</li> <li>Output signal 8-12.5 mV</li> <li>Response time:: &lt; 15 seconds</li> <li>Warranty: 16 months</li> <li>Storage: up to 6 months</li> </ul>	<ul> <li>Connector: 3 pin Molex</li> <li>Measuring Range: 0- 100%</li> <li>Output Signal: 10-13mV</li> <li>Response time: 4 seconds</li> <li>Warranty: 12 months</li> <li>Storage: up to 6 months</li> <li>currently n/a</li> </ul>	<ul> <li>Connector: 3-pin Molex</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 11-14 mV</li> <li>Response time: &lt; 12 seconds</li> <li>Warranty: 12 months</li> <li>Storage: up to 3 months</li> </ul>	<ul> <li>Connector: 3.5 mm mono jack</li> <li>Flow diverter to be ordered seperately</li> <li>Measuring range: 0- 100% O<sub>2</sub></li> <li>Output signal: 13–16-5 mV</li> <li>Response time: &lt; 12 seconds</li> <li>Warranty: 16 months</li> </ul>

• Storage: up to 6 months



#### E-17/M

- Connector: 3-pin Molex
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 12.5-16.5 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months



E-25/0

- Connector: straight power jack
- Measuring range: 0-100% O2
- Output signal: 9–14.5 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months



E-33/0

Ε

- Connector: gold plated
   Contact rings
- Measuring range: 0-100% O2
- Output signal: 200 μA
- Response time: < 20 seconds
- Warranty: 16 months
- Storage: up to 3 months



Connector: double wired
 PCB plug

- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 200 µA
- Response time:< 20 seconds
- Warranty: 16 months
- Storage: up to 3 months



#### E-43/0

- Connector: gold plated contact rings
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 25–35.5 mV
- Response time: < 17 seconds
- Warranty: 12 months
- Storage: up to 3 months



#### E-47/0

- AMP phone jack 4P4C
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: in accordance with Hudson
- 5801 analyzer
- Response time: < 12 seconds
- Warranty: 16 month

- Connector: 4-pin male
  - Connector: 4-pin male socket
  - Measuring range: 0-100% O<sub>2</sub>
  - Output signal: 250-650nA
  - Response time: < 15 seconds
  - Warranty: 16 months
  - Storage: up to 4 months



#### E-60/0

E-33/1

- Connector: AMP phone jack
- Flow diverter to be ordered seperately
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 3.8-4.8 mV
- Response time: < 12 seconds
- Waranty: 16 months

• always 2 pcs per pack

• Storage: up to 6 months

• Storage: 4 months



#### E-60/LF (LONG LIFE SENSOR)

- Lead-free, ROHS compliant
- Connector: 3 pin Molex
- Measuring range: 0-100%
- Output signal: 0.8-1.25 V
- Response time: < 5 seconds
- Warranty: 24 months
- Storage: up to 6 months



#### E-75/A

- Connector: AMP phone jack
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8.5 13.5 mV
- Response time: < 15 seconds
- Warranty: 24 months
- Storage: up to 6 months
- currently n/a



#### E-75/1

- Connector: AMP
- Measurng range: 0-100% O<sub>2</sub>
- Output signal: 10 14 mV
- Response time: < 13
   seondcs
- Warratny: 22 months
- Storage: up to 6 months
- currently n/a



- Connector: NESJ25
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 10-14 mV
- Response time < 13 seconds
- Warranty: 22 months
- Storage: up to 6 months
- currently n/a



#### E-75/6 and E-75/8

- Connector: E-75/KE6: SM2SH 2pol
- Connector: E-75/KE8: IP40 3pol
- Measruring range: 0-100% O<sub>2</sub>
- Output signal: 10-14 mV



#### 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



#### E-75/13PB

- compatible to Puritan Bennett sensor PB10097559
- currently n/a

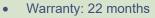
- Response time: < 13 seconds
- Warranty and Storage as E-75/4
- currently n/a



E-75/HL

- Connector: 3 pin phone connector
- Measuring Range: 0-100% O
- Output signal: 10-13.5mV
- Response time: 13 seconds
- Warranty: 15 months
- Storage: up to 6 months
- currently n/a

- Connector: RJ11
   modular
   plug 4P4C
- Flow diverter to be ordered sperately
- Measuring range: 0-100% O2
- Output signal: 7.5–13.0 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months



- Storage: up to 6 months
- with flow diverter
- currently n/a



E-77/0S

- Connector: RJ11
   modular jack
- Flow diverter to be ordered seperately
- 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



E-8000

Е

- Connector: 3 gold plated contact rings
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 14.5–20 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months

Contact Nuova®

## EC CERTIFICATE for the Quality Assurance System

### according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

### IT Dr. Gambert GmbH

Hinter dem Chor 21, 23966 Wismar, Germany Certified location: Hinter dem Chor 21, 23966 Wismar, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50403-Z6-00, the decision dated 2018-08-31 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-09-17 to 2023-09-16

Registration No.: 50403-16-07



Ruth Delberk-Bayer Wart, Handreit DEKRA Certification GmbH Stuttgart; 2018-08-31 Notified Body ID-number: 0124



DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra-certification.de

### Annex to the EC Certificate No. 50403-16-07

Valid from 2018-09-17 to 2023-09-16

Revision status of the annex: 0 dated 2018-08-31

Devices/device categories included in the certificate:

<u>Class II a:</u>

- Oxygen sensors
- Nitric oxide sensors



Ruth Delbeck-Bayer DEKRA Certification GmbH, Stuttgart, 2018-08-31 Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra-certification.de

# CERTIFICATE

## EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

#### IT Dr. Gambert GmbH

#### Scope of certification:

DEKRA

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-Z7-00.

Certificate registration no.: Validity of previous certificate: 50403-14-01 C 2021-09-16 C

Certificate valid from: Certificate valid to: 2021-09-28 2024-09-16

Chart DEKRA

Ruth Delbeck-Bayer DEKRA Certification GmbH, Stuttgart, 2021-09-28



DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra.de/audits

page 1 of 1

# CERTIFICATE

## EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

#### IT Dr. Gambert GmbH

#### Scope of certification:

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

#### **Certified location:**

DEKRA

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-Z7-00.

Certificate registration no.: Validity of previous certificate: 50403-14-01 C 2021-09-16 C

Certificate valid from: Certificate valid to: 2021-09-28 2024-09-16

Chart DEKRA

Ruth Delbeck-Bayer DEKRA Certification GmbH, Stuttgart, 2021-09-28



DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra.de/audits

page 1 of 1

#### PRODUCT MATCH LISTE NUOVA GMBH und IT-Wismar, WISMAR MEDICAL OXYGEN SENSORS Version 19.02.2020

It-Wismar Artikel Nr.	Nuova Artikel Nr.
M-09	E-09/0
M-11	E-11/0
M-14	E-14/0
M-14/ST	E-14/S
M-01	E-15/0
M-02 (M02L2 US Version, weisses Gehäuse)	E-15/2
M-10	E-15/4
M-15	E-15/5
M-15/M	E-15/5M
M-16	E-16/0
M-16HTT	E-16/HTT
M-12	E-17/A2
M-12A	E-17/A2A
M-80	E-17/A4
M-03	E-17/J
M-04	E-17/M
M-25	E-25/0
M-05	E-33/0
M-06	E-33/1
M-43	E-43/0
M-47	E-47/0
M-13	E-55/0
M-48	E-60/0
MLF-60HC	E-60LF
M-07	E-77/0
M-07S	E-77/0S
M-08	E-8000

Siehe auch websites <u>www.nuova.de</u>, <u>www.it-wismar.de</u>

S. Schneider Ratzeburg, 19.02.2020

#### EC Declaration of Conformity

## ∵...≋ıtg

Herewith we ensure and declare in the sole responsibility that the product(s), listed below, meet the provisions for total quality management system according the EC-Council Directive 93/42/EEC, Annex II excluding section 4, and its essential requirements according to Annex I.

Company:

IT Dr. Gambert GmbH Hinter dem Chor 21 23966 Wismar Germany

Manufacturer: IT Dr. Gambert GmbH Hinter dem Chor 21 23966 Wismar Germany

Product category: Oxygen Sensors / O2-Sensor

Type/Indication itg:		
M-01	41 00 01	
M-02L2	41 01 02	
M-03 incl. Flow Diverter	41 03 03	
M-04	41 00 06	
M-04C	41 02 06	
M-05	41 00 07	
M-06	41 00 08	
M-07	41 00 09	
M-075	41 01 09	
M-08	41 00 12	
M-09	41 00 23	
M-10	41 00 14	
M-11	41 00 15	
M-12	41 00 17	
M-12A	41 02 17	
M-13	41 00 18	
M-14	41 00 19	
M-14ST	41 02 19	
M-15	41 00 23	
M-15M	41 06 23	
M-16	47 00 16	

Documentversion:	12		Date:	04.01.21	
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#### EC Declaration of Conformity

## ∴..≋ıtg

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M-16HTT	47 02 16
M-25	41 00 20
M-43	41 00 04
M-47	41.00 27
M-48 Incl. Flow Diverter	41 01 28
M-80	41 00 31
MLF-16	47 03 16
MLF-60HC	41 00 40

Classification:

#### r: Class lle device

(according to EC-Council Directive 93/42/EEC Annex IX Rule 2)

Notified Body:

DEKRA Certification GmbH Handwerkstraße 15 70565 Stuttgart Germany

NB-Code. 0124

CE certificate registration No.: 50 valid until: 16 Date of Initial certification: 31

50403-16-07 16-09-2023 31-08-2003

Wismar, 04.01.2021

#### CEO Hinter dem Char 21 23966 Wismar, Germany Phone: +49-(0)-3841-22 00 50 Fax: +49-(0)-3841-22 00 522

Demian Gambert

Documentversion:	12	Date:	04.01.21