

#### E-09/0

- Connector: 3-pin wired Molex
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 9.5–14 mV
- Response time: < 18 seconds</li>
- Warranty: 16 months
- Storage: up to 6 months



#### E-11/0

- Connector: AMP350777 1
  - 2 way mating lock
- Measuring Range: 0-100% O<sub>2</sub>
- Output signal: 8.5-12.5mV
- Response time: < 17 seconds
- Warranty: 16 months
- Storage: up to 6 months



E-14/0

- Connector: 0.141"
   miniature phone plug on cable
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8–12 mV
- Response time: < 17 seconds</li>
- Warranty: 16 months
- Storage: up to 6 months



E-14/S

- Connector: phone plug with cable
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8-12 mV
- Response time: < 17 seconds
- Warranty: 16 months
- Storage: up to 6 months



#### E-15/0

- Connector: 3 contact rings gold plated
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 14–20 mV
- Response time:< 17 seconds</li>
- Warranty: 16 months



#### 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



#### E-15/4

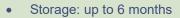
- Connector: modular jack
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8–12 mV
- Response time: < 16 seconds</li>
- Warranty: 16 months



E-15/5

- Connector: 3.5 mm mono 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

#### • Storage: up to 6 months



#### E-15/5M

 specification as E-15/5 however different housing to fit for Mindray WATO



#### E-16/0

- Connector: 3-pin Molex
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 9.5-16 mV
- Response time: < 12 seconds
- Warranty: 16 months
- Storage: up to 6 months



**E-16/HTT** 

- Connector: 3-pin Molex
- Measuring range: 0-100% O<sub>2</sub>
- 9.5-16 mV
- Response time: 12 s at flow >2I/min
- Warranty: 12 months
- Storage: up to 6 months



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-17/A2A

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



#### E-17/A2MH3

- Connector: 3 pin Molex
- Measuring Range: 0-100%
- Output Signal: 10-13mV
- Response time: 4 seconds
- Warranty: 12 months
- Storage: up to 6 months
- currently n/a



#### 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-17/J

- Connector: 3.5 mm mono jack
- Flow diverter to be ordered seperately
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 13–16-5 mV
- Response time: < 12 seconds
- Warranty: 16 months

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
- Response time: < 12 seconds</li>
- 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

- 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



E-33/1

- Connector: double wired PCB plug
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 200 μA
- Response time:< 20 seconds</li>
- 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</li>
- 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



E-55/0

- 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

- 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</li>
- Waranty: 16 months



• 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</li>
- 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</li>
- Warratny: 22 months
- Storage: up to 6 months
- currently n/a



E-75/4

- 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

- Warranty: 22 months
- Storage: up to 6 months
- with flow diverter
- 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



E-77/0

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



#### 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

- 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



## 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



DEKRA Certification GmbH Stuttgart; 2018-08-31

Notified Body ID-number: 0124

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



Benannt durch/Designated by

Zentralstelle der Länder 🥞 für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

ZLG-BS-295.10.02

### 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:

#### Class II a:

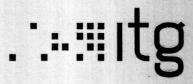
- Oxygen sensors
- Nitric oxide sensors



DEKRA Certification GmbH, Stuttgart, 2018-08-31

Notified Body ID-number: 0124

### **EC Declaration of Conformity**



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	/Indicatio	n 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-07S	`	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	

是一种" <b>对某种发生"。</b>				
Documentversion:		12	Date:	04.01.21
		<b>经验证证明的证明</b> 证明		

### **EC Declaration of Conformity**



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:

Class lla 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.:

50403-16-07

valid until:

16-09-2023

Date of Initial certification:

31-08-2003

Wismar, 04.01.2021

Demian Gambert CEO

IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar. Germany
Phone: +49-(0)-3841-22 00 50
Fax: +49-(0)-5841-22 00 522

## 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:

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.: 50403-14-01 Certificate valid from: 2021-09-28 Validity of previous certificate: 2021-09-16 Certificate valid to: 2024-09-16



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



## 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:

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.: 50403-14-01 Certificate valid from: 2021-09-28 Validity of previous certificate: 2021-09-16 Certificate valid to: 2024-09-16



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



### 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 www.nuova.de, www.it-wismar.de

S. Schneider Ratzeburg, 19.02.2020