



E-17/M

- Connector: 3-pin Molex
- Measuring range: 0-100% O₂
- Output signal: 12.5-16.5 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

Ruth Delbeck-Bayer



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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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


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



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



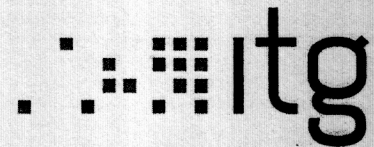
PRODUCT MATCH LISTE NUOVA GMBH und IT-Wismar, WISMAR
MEDICAL OXYGEN SENSORS
Version 19.02.2020

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

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

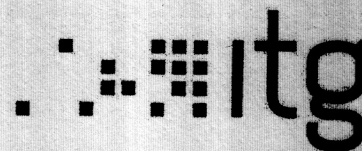
Manufacturer: IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar
Germany

Product category: Oxygen Sensors / O2-Sensor

Type/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-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

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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 IIa 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

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

A handwritten signature in black ink, appearing to read 'Demian Gambert', is written over the printed name and title.

Documentversion:	12	Date:	04.01.21
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