

E



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 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
ZLG-BS-295.10.02
www.zlg.de

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

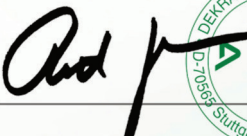
Valid from 2018-09-17 to 2023-09-16

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

Devices/device categories included in the certificate:

Class II a:

- Oxygen sensors
- Nitric oxide sensors

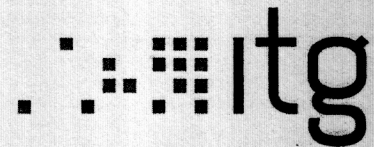


DEKRA Certification GmbH
Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
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Notified Body ID-number: 0124

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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

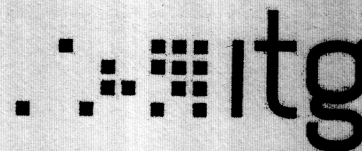
Manufacturer: IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar
Germany

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

Documentversion:	12	Date:	04.01.21
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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

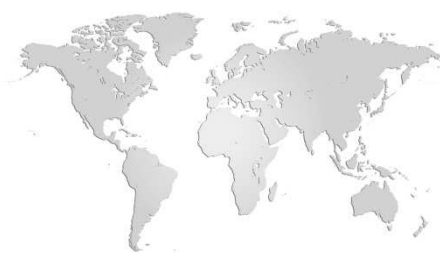
IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar, Germany
Phone: +49-(0)-3841-22 00 50
Fax: +49-(0)-3841-22 00 522

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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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