

## Manufacturer's Declaration

for Class IIa  
**Oxygen sensors**  
**Nitric oxide sensors**

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

|  |  |
|--|--|
| Manufacturer name                        | IT Dr. Gambert GmbH                            |
| Manufacturer address and contact details | Hinter dem Chor 21,<br>23966 Wismar<br>Germany |
| Single Registration Number (SRN)         | DE-MF-000004930                                |

|   |                          |
|---|--------------------------|
| Notified body name  | Dekra Certification GmbH |
| Notified body number  | 0124                     |
| Directive Certificate number to which this confirmation is made                                       | 50403-16-07              |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity | 16.09.2023               |
| End date of extended validity/transition period   | 31.12.2028               |

### IT DR. GAMBERT GMBH

Hinter dem Chor 21  
23966 Wismar  
Germany

Phone +49 (0) 3841 / 22 00 50  
 Fax +49 (0) 3841 / 22 00 546  
 E-Mail [info@itg-wismar.de](mailto:info@itg-wismar.de)

Geschäftsführer /  
 Chief Executive Officer  
 Demian Gambert

HR Schwerin · HRB 5857  
 USt-IdNr. / VAT DE 812438178

### Bankverbindungen / Bank Accounts

Deutsche Bank AG Wismar  
 BLZ 130 700 00  
 Konto 273 577 700  
 BIC DEUTDE33  
 IBAN DE91 1307 0000 0273 5777 00

Sparkasse Mecklenburg-Nordwest  
 BLZ 140 510 00  
 Konto 100 001 5609  
 BIC NOLADE21WIS  
 IBAN DE57 1405 1000 1000 0156 09

Commerzbank AG  
 BLZ 140 800 00  
 Konto 212 119 000  
 BIC DRESDEFF 140  
 IBAN DE73 1408 0000 0212 1190 00

[www.itg-wismar.de](http://www.itg-wismar.de)

We, as manufacturer, declare under our sole responsibility:

- for the listed guideline certificate the conditions for the legal extension of validity according to Article 120.2 of the MDR are fulfilled, and
- we, as its manufacturer, comply with the conditions for continued placing on the market and putting into service set out in Article 120.3c of the MDR,

by complying with the following conditions:

➤ **Directive Certificate**

The directive certificate for the products was issued after May 25, 2017, was valid on May 26, 2021, and has not been revoked thereafter.

A formal application(s) for conformity assessment to the Notified Body in accordance with the first subparagraph of Section 4.3 of Annex VII of the MDR has been submitted by us by May 26, 2024 for the listed devices and a signed written agreement in accordance with the second subparagraph of Section 4.3 of Annex VII of the MDR is in place prior to September 26, 2024.

➤ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➤ **Further**

- The products continue to comply with the AIMDD or MDD.
- There are no significant changes in design or intended use.
- The products do not pose an unacceptable risk to the health or safety of patients, users or others, or to other aspects of public health protection.

**Signed for and on behalf of the manufacturer:**

|                        |  |
|------------------------|--|
| Full Company Name      | IT Dr. Gambert GmbH  |
| Location , Date        | Wismar, 16.08.2023   |
| Contact Details        | <a href="mailto:demian.gambert@itg-wismar.de">demian.gambert@itg-wismar.de</a> |
| Name Managing Director | Demian Gambert   |

Sources: *Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023*  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R0607>

Appendix: - EC CERTIFICATE for the Quality Assurance System according to the Directive 93/42/EEC, Annex II excluding section (4)  
- Certificate EN ISO 13485:2016

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# 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  
DEKRA Certification GmbH Stuttgart; 2018-08-31  
Notified Body ID-number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://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



A handwritten signature in black ink, appearing to read 'Ruth', is written over a horizontal line.



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](http://www.dekra-certification.de)

# 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



# 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

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

Registration No.: 50403-16-07



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



Benannt durch/Designated by  
Zentralstelle der Länder  
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bei Arzneimitteln und  
Medizinprodukten  
**ZLG-BS-295.10.02**  
[www.zlg.de](http://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



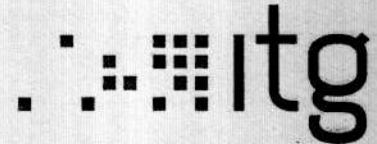
*Ruth Delbeck-Bayer*



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](http://www.dekra-certification.de)

## 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

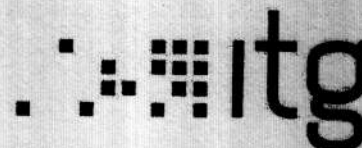
**Product category:** Oxygen Sensors / O2-Sensor

| 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 |
|------------------|----|-------|----------|



# 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

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Demian Gambert  
CEO

|                  |    |       |          |
|------------------|----|-------|----------|
| Documentversion: | 12 | Date: | 04.01.21 |
|------------------|----|-------|----------|