itg · Hinter dem Chor 21 · 23966 Wismar · Germany

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, 23966 Wismar 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

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23966 Wismar
Germany

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E-Mail 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 DEUTDEBR
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

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BIC DRESDEFF 140
IBAN DE73 1408 0000 0212 1190 00

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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	demian.gambert@itg-wismar.de
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 the Directive 93/42/EEC, Annex II excluding section (4)*
- *Certificate EN ISO 13485:2016*

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 • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

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
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 • Handwerkstraße 15 • D-70565 Stuttgart

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

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

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

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.

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Ruth Delbeck-Bayer
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/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

itg

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

Demian Gambert
CEO

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