

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



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Stuttgart, Handwerkstraße 15

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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

