

# CERTIFICATE

Number: 2255277

The management system of:

## IT Dr. Gambert GmbH

Hinter dem Chor 21  
23966 Wismar  
Germany

Manufacturer Facility Identifier F004450

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

### Scope:

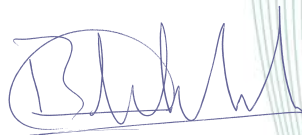
Design and development, manufacture and distribution of electro-chemical gas sensors for medical equipment.

Certificate expiry date: 2027-03-01

Certificate effective date: 2024-05-16

Certified since: 2021-03-26

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:

<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



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