

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

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50403-Z5-00, the decision dated 2015-09-16 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2015-09-17 to 2018-09-16

Certificate registration No.: 50403-16-06



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

DEKRA Certification GmbH Stuttgart; 2015-09-16
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50403-16-06 dated 2015-09-16

Revision status: 0

Date: 2015-09-17

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Devices/device categories included in the certificate

Class II a:

- Oxygen sensors
- Nitric oxide sensors

