Manufacturer's Declaration

for Class IIa
Oxygen 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

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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

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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The directive certificate for the products was issued after May 25, 2017, was valid on May 26, 2021, and has not been revoked thereafter.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 or formal applications for conformity assessment with the Notified Body in accordance with Annex VII Section 4.3 subparagraph 1 of the MDR has been submitted by us by May 26, 2024 for the listed devices. The receipt of the application was confirmed by the notified body. A written agreement in accordance with Regulation (EU) 2017/745 Annex VII Section 4.3 subparagraph 2 shall be signed by 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, 28.05.2024
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*

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