EC Declaration of Conformity

Herewith we ensure and declare in the sole responsibility that the product(s), listed below, meet the provisions according to the Regulation 2017/745/EU Article 120. And have meet the 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
Models : See Annex I

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, 20.05.2021

Demian Gambert
CEO

IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar, Germany
Phone: +49-(0)-3841-22 00 50

EC Declaration of Conformity Annex I

Validity of aforementioned EC Declaration of Conformity, dated 20.05.2021

As the mentioned validity of the relevant CE Certificate expired on September 17th 2023, the validity of the EC-DoC and the certificate was prolonged by law through Regulation (EU) 2023/607 amending Regulations(EU) 2017/745 until latest of September 26th 2024.
From that date on a confirmation on the status of a formal application, written agreement, and appropriate
surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 in regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices is needed to prolong the validity of certificates and EC Declaration of Conformity that were issued prior to that date.

Please find attached the confirmation on the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 in regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices from our notified body.

Therefor the validity of aforementioned EC Declaration of Conformity, dated 20.05.2021, and it's scope are extended to the applicable dates and Annexes of the attached confirmation letter.

Wismar, 05.11.2025

Demian Gambert
CEO

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

IT Dr. Gambert GmbH
Herr Demian Gambert
Hinter dem Chor 21
23966 Wismar
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Elena Schröder
Phone -
Fax +49.711.7861-2615
Email elena.schroeder@dekra.com

Headquarters
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Fax +49.711.7861-2615

Date 2025-10-31

Subject: Notified Body Confirmation Letter

Our reference: 50403-CoL-01 Rev. 1

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Gambert

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

IT Dr. Gambert GmbH
Hinter dem Chor 21
23966 Wismar
Deutschland

SRN Number: DE-MF-000004930

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Validity of this confirmation letter:

For products included in table 1

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607)

On behalf of the Notified Body,

Elena Schröder

Digitally signed by Elena Schröder
Date: 2025-10-31 15:17:23+01:00

Elena Schröder
2025/10/31

Enclosures:

Confirmation Letter Annex

Table 1:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medical oxygen sensor M-01	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-01L2	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-01T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-01TL2	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-02	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-02L2	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-02T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-02TL2	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-03	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-03 incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-03HDM incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-03T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-03T incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-04	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-04T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-04C	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-04CT	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-05	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-06	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-07 incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-07T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-07S	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-07ST	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-08	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-08T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-09	Class IIa	N/A	Certificate 50403-16-07

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medical oxygen sensor M-09T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-09F	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-09M	Class IIa	N/A	Certificate 50403-16-07
Medical xygen sensor M-10	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-11	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-12	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-12 incl. translucent Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensors M-12 Doppelpack	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-12A	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-12A Doppelpack	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-12T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensors M-13	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-14	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-14T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-14TB	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-14ST	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15 incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15T incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15TL incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-15M	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-16	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-16T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-16HT	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-16HTT	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-16PT	Class IIa	N/A	Certificate 50403-16-07

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medical oxygen sensor M-16VT	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-18T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-25	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-25 incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-25T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-25T incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43 Doppelpack	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43T	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43T Doppelpack	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43GE	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-43GE Dual Pack	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-44	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-44PI	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-45	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-47	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-48	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-48 incl. Flow Diverter	Class IIa	N/A	Certificate 50403-16-07
Medical oxygen sensor M-80	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-03	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-04	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-07M	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-11	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-11K	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-12A	Class IIa	N/A	Certificate 50403-16-07

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Lead-free Medical oxygen sensor MLF-15	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-15M	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16D	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16DD	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16DE	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16H	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-16HL	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-17	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-19	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-19GE	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-42HL	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-43	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-44	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-44PI	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-45H	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-60 HC	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-80	Class IIa	N/A	Certificate 50403-16-07
Lead-free Medical oxygen sensor MLF-80HL	Class IIa	N/A	Certificate 50403-16-07