SLG Prüf- und Zertifizierungs GmbH

Certificate

Company:	Medlab medizinische Diagnosegeräte GmbH Helmholtzstraße 1a 76297 Stutensee, Germany
Certificate number:	110826M8A
Audit report:	5088-23-PP-24-QB001
Valid from:	2024-04-03
Valid until:	2026-09-18

SLG Prüf- und Zertifizierungs GmbH certifies
that the above mentioned company has implemented and uses
a quality management system covering the scope of

Development, manufacturing, production and distribution of medical diagnostic equipment

in accordance with the requirements of

DIN EN ISO 13485:2021-12
(ISO 13485:2016)

DAkkS Deutsche Akkreditierungsstelle D-ZM-15110-01-00

SLG Prüf- und Zertifizierungs GmbH SLG ZERTIFIZIERUNGS-STELLE

Hartmannsdorf, 2024-04-03
SLG file no.: 5088-23-PP

D. Eisentraut
Certification Body

SLG Prüf- und Zertifizierungs GmbH
Burgstädter Straße 20
09232 Hartmannsdorf · Germany
Tel.: +49 3722 7323-0
Fax: +49 3722 7323-899
service@slg.de.com
www.slg.de.com

SLG Prüf- und
Zertifizierungs GmbH

EG-Zertifikat
EC Certificate

Vollständiges Qualitätssicherungssystem
Full Quality Assurance System

Richtlinie 93/42/EWG für Medizinprodukte, Anhang II ohne Abschnitt 4 (Klasse IIa und IIb-Produkte)
Directive 93/42/EEC on Medical devices, Annex II excluding section 4 (Class IIa and IIb Devices)

Produkt / Kategorie(n) **Product / Category(ies):**	Kapnographen, Puls-Oximeter und Vitalzeichen-Monitore mit NIBP sowie Zubehör | Capnographs, pulse oximeters, vital sign monitors with NIBP and accessories
Liste der Produkte siehe Anlage **List of products see annex**	UMDNS: 16-938, 17-148, 17-678, 17-594 — Klassifizierung / Classification: IIa/IIb
Hersteller **Manufacturer:**	Medlab Medizinische Diagnosegeräte GmbH Helmholtzstraße 1a 76297 Stutensee b. Karlsruhe, Deutschland / Germany
Zertifikats-Nr. **Certificate no.:**	109973N2
Gültig ab **Valid from:**	19.09.2019
Gültig bis **Valid until:**	25.05.2024

Die Benannte Stelle 0494 SLG Prüf- und Zertifizierungs GmbH bescheinigt der zuvor genannten Firma die Anwendung eines Qualitätssicherungssystems für Auslegung, Herstellung und Endkontrolle der entsprechenden Produkte / Produktkategorien nach Medizinprodukte-Richtlinie Anhang II.

The Notified Body 0494 SLG Prüf- und Zertifizierungs GmbH declares that the aforementioned company has implemented a quality assurance system for design, manufacturing and final inspection of the respective devices / device categories in accordance with the Medical Device Directive Annex II.

Die Einhaltung der anwendbaren Anforderungen des Anhang II wurde bewertet in:
Compliance with the applicable requirements of Annex II was reviewed in:

Auditabschlussbericht
Final Audit Summary Report: SLG - 5066-17-PP-19-QB001

Das zuvor beschriebene Qualitätssicherungssystem unterliegt der regelmäßigen Überwachung gemäß Anhang II Abschnitt 5.
The quality assurance system described above is subject to periodic surveillance in accordance with Annex II section 5.

Hartmannsdorf, 10. September 2019
SLG file no.: 5066-17-PP

SLG Prüf- und Zertifizierungs GmbH
SLG
ZERTIFIZIERUNGS-STELLE

M. Herrig
Zertifizierungsstelle
Certification Body

SLG Prüf- und Zertifizierungs GmbH
Burgstädter Straße 20
09232 Hartmannsdorf · Germany
Tel.: +49 3722 7323-0
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www.slg.de.com

Anlage zu Zertifikat Nr.
Annex to certificate no.: 109973N2

Revision: 0

Hersteller
Manufacturer:

Medlab Medizinische Diagnosegeräte GmbH
Helmholtzstraße 1a
76297 Stutensee b. Karlsruhe, Deutschland / Germany

Liste der im Zertifikat enthaltenen Produkte
List of products covered by the certificate

Produkt Product	Typ Type	Klassifizierung Classification	UMDNS
Atemgas CO2-Monitor | Exhaled Gas Carbon Dioxide Monitor	CAPNOX CAPNOS CAP10	IIb	16-938
Puls-Oxymetergerät | Pulse-Oximeter-Equipment	PEARL 5/8 PEARL100L P-OX100L VITROmap	IIb	17-148
Vitalzeichen-Monitor | Vital Signs Monitor	VITRO	IIb	17-678
Pulspximeter Applikator | Puls-Oximeter-Probe	P-200, PX-200, PS-200, R-200, RS-200, WR-200, Y-200	IIa	17-594
Einmal-Pulsoximeter Applikator | Disposal-Pulse-Oximeter-Probe	"Adult, Plaster, "Child, Plaster, "Infant, Plaster, "Neonate, Plaster	IIa	17-594

SLG Prüf- und Zertifizierungs GmbH
SLG
ZERTIFIZIERUNGS-STELLE

Hartmannsdorf, 10. September 2019
SLG file no.: 5066-17-PP

M. Herrig
Zertifizierungsstelle
Certification Body

SLG Prüf- und Zertifizierungs GmbH

Unser Zeichen	Bearbeiter	Datum
24-P-Schu-0021	Kerstin Schulze (Tel.: +493722 73 23-797) (E-Mail: k.schulze@slg.eu)	08.04.2024

Notified Body Confirmation Letter

Reference: 24-P-Schu-0021

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SLG Prüf- und Zertifizierungs GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 0494 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:

Medlab medizinische Diagnosegeräte GmbH

Helmholtzstraße 1a

76297 Stutensee

SRN Number (if available): DE-MF-000018583

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 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. 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.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or 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/AIMDD 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)

This confirmation shall be renewed regularly and is valid until: 2025-10-01

On behalf of the Notified Body,
CE 0494

SLG Prüf- und Zertifizierungs GmbH
SLG
ZERTIFIZIERUNGS-STELLE

08.04.2024

Dirk Eisentraut
Certification Body Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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
CAP10	Class IIb	N/A	Certificate CE0494: 109973N2
PEARL 5	Class IIb	PEARL 5/8	Certificate CE0494: 109973N2
PEARL 8	Class IIb	PEARL 5/8	Certificate CE0494: 109973N2
PEARL100L	Class IIb	N/A	Certificate CE0494: 109973N2
P-OX100L	Class IIb	N/A	Certificate CE0494: 109973N2
VITROmap	Class IIb	N/A	Certificate CE0494: 109973N2
VITRO	Class IIb	N/A	Certificate CE0494: 109973N2
P-200	Class IIa	N/A	Certificate CE0494: 109973N2
PX-200	Class IIa	N/A	Certificate CE0494: 109973N2
PS-200	Class IIa	N/A	Certificate CE0494: 109973N2
R-200	Class IIa	N/A	Certificate CE0494: 109973N2
Y-200	Class IIa	N/A	Certificate CE0494: 109973N2
DIS-200AP	Class IIa	Adult, Plaster	Certificate CE0494: 109973N2
DIS-200CP	Class IIa	Child, Plaster	Certificate CE0494: 109973N2
DIS-200IP	Class IIa	Infant, Plaster	Certificate CE0494: 109973N2
DIS-200NP	Class IIa	Neonate, Plaster	Certificate CE0494: 109973N2

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-28	24-P-Schu-0020	Initial issue
2024-04-08	24-P-Schu-0021	Addition of device R-200 to the list

EU-KONFORMITÄTSERKLÄRUNG/ EU DECLARATION OF CONFORMITY

medlab

medizinische Diagnosegeräte GmbH

Name und Adresse des Unternehmens / Name and address of company	**Medlab medizinische Diagnosegeräte GmbH** **Helmholtzstraße 1a** **76297 Stutensee** **Germany**
SRN	**DE-MF-000018583**

Wir erklären, dass wir als Hersteller die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung tragen. / We declare that we as the manufacturer are solely responsible for issuing this declaration of conformity.

Medizinprodukt / Medical Device	**CO2 Absaugleitungen und T-Adapter für Kapnographen /** CO2-Sampling lines and T-connector for Capnographs
Zweckbestimmung / Intended purpose	**CO2-Zubehör für den Einmalgebrauch mit Medlab Kapnographen** / CO2 accessories for single use with Medlab capnographs
Basis UDI-DI / Basic UDI-DI	**426041842CO2ACCVC**

Modelle / Models

REF	**Product Name**
08001	CO2-Sampling line, universal
08002	Nasal CO2-Sampling cannula for neonates
08003	CO2-Sampling line with T-connector for endotracheal tube
08004	T-Connector for endotracheal tube
08008	Nasal CO2-Sampling cannula for adults and children

Risikoklasse / Risk class	**Medizinprodukt der Klasse I /** Medical device of class I

Die von dieser Erklärung erfassten Geräte entsprechen der Verordnung (EU) 2017/745 (MDR). / The devices covered by this declaration are in conformity with regulation (EU) 2017/745 (MDR).

Angewandte Gemeinsame Spezifikationen / Common Specifications Applied	**Noch nicht bereitgestellt /** Not yet provided
Konformitätsbewertungsverfahren nach / Conformity assessment acc. to	**Bewertung der Technischen Dokumentation gemäß Anhang II und III MDR durch den Hersteller /** Evaluation of the technical documentation according to Annex II and III MDR by the manufacturer

Beginn der Gültigkeit / Valid from:
Datum / Date: **19.01.2022**
Ende der Gültigkeit / Valid until:
Datum / Date: **25.05.2025**
Ort / City: **Stutensee**

CE

19.01.2022

Datum / Date

ppa. Dr. Thomas Reiß

Unterschrift / Signature
Dr. Thomas Reiß
Stellvertretung der Geschäftsführung / Assist. Managing Director