Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 126839 0002 Rev. 00

Manufacturer:

Linde Gas Schweiz AG
Industriepark 10
6252 Dagmersellen
SWITZERLAND

SRN Manufacturer - CH-MF-000044437

Authorized Representative:

Linde GmbH Gases Division
Seitnerstr. 70, 82049 Pullach, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G26 126839 0002 Rev. 00

Report No.: 713342060
Valid from: 2025-09-04
Valid until: 2030-09-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-09-04

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Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 126839 0002 Rev. 00

Classification:	Class IIa
Device Group:	MDN 1213 - Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route
Classification:	Class IIa
Device Group:	MDA 0303 - Active non-implantable devices utilising hyperthermia/hypothermia
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-09-04	713342060	Initial issuance

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