

EU Quality Management System Certificate

Certificate no.
1332GB448241212

Final Assessment Report no.
1332AU27F

Effective date
2024-12-12

Expiry date
2028-06-10

This is to certify that the quality system of

VTI Ventil Technik GmbH

Iserlohner Landstraße 119, 58706 Menden, Germany

SRN: DE-MF-000006534

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-12-12

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com


Annika Chill
Certification Body



DNV

Certificate no.: [1332GB448241212](#)
Place and date: [Hamburg, 2024-12-12](#)

Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

Sites covered by this certificate

VTI Ventil Technik GmbH, Iserlohner Landstraße 119, 58706 Menden, Germany





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Products covered by this certificate

Class IIb medical devices, excluding implantable non-WET*

Category	EMDN code	Medical devices/groups of medical devices
MDA 0316	R9080	RESPIRATORY AND ANESTHESIA DEVICES - ACCESSORIES NOT INCLUDED IN OTHER CLASSES

Intended purpose

Pressure / flow control medical gases

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.

