

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
1320GB448260630

Final Assessment Report no.
1320AU33F

Effective date
2026-06-30

Expiry date
2028-06-05

This is to certify that the quality system of

Andreas Fahl Medizintechnik-Vertrieb GmbH

August-Horch-Straße 4a, 51149 Köln, Germany

SRN: DE-MF-000006665

For design & development, manufacturing and final product inspection/testing of
Medical devices/groups of medical devices at locations as 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, 2026-06-30

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Brooktorkai 18, 20457 Hamburg, Germany



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



Marcus Harder
Certification Body Operations

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



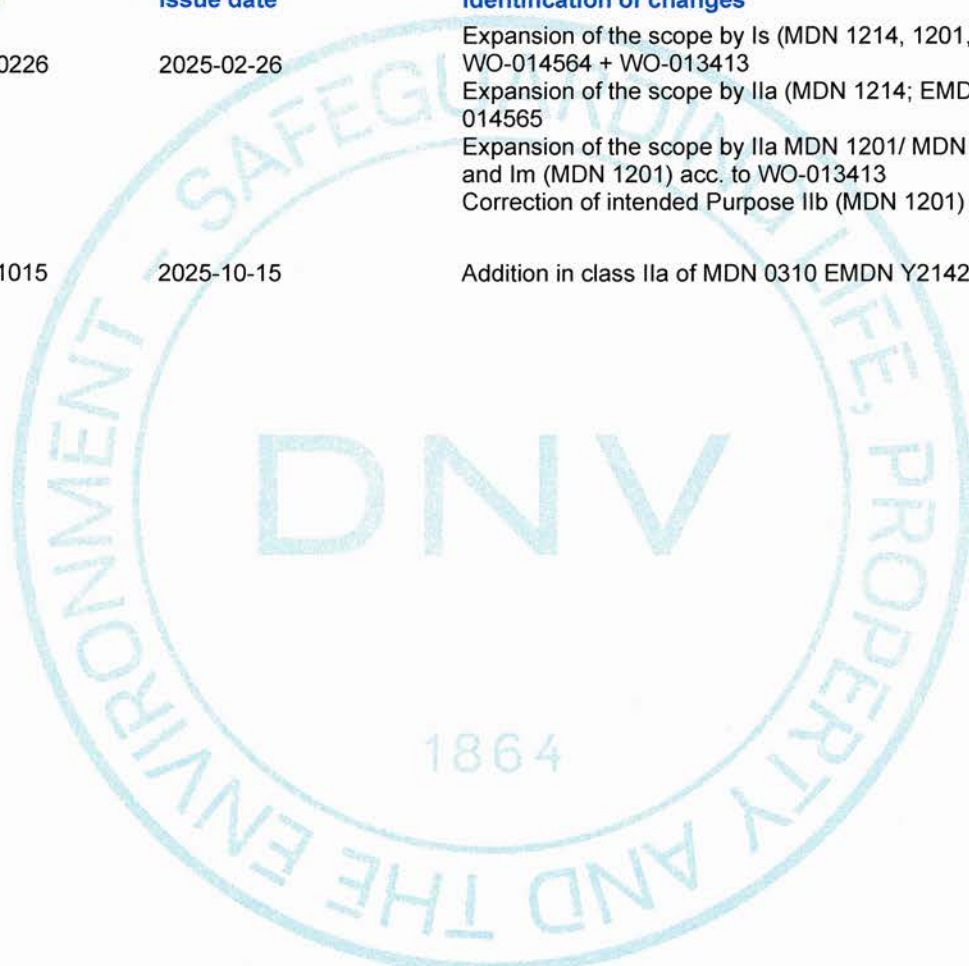
Certificate no.: 1320GB448260630
Place and date: Hamburg, 2026-06-30

Sites covered by this certificate

Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 4a, 51149 Köln, Germany
Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 6, Germany
Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 6b, Germany
Andreas Fahl Medizintechnik-Vertrieb GmbH, Am Borsigturm 62, 13507 Berlin, Germany

Preceding certificate

Certificate no.	Issue date	Identification of changes
1320GB448250226	2025-02-26	Expansion of the scope by Is (MDN 1214, 1201, 1203) acc. to WO-014564 + WO-013413 Expansion of the scope by IIa (MDN 1214; EMDN R9009) acc. to WO-014565 Expansion of the scope by IIa MDN 1201/ MDN 1203 (EMDN R0106) and Im (MDN 1201) acc. to WO-013413 Correction of intended Purpose IIb (MDN 1201) acc. to WO-014673
1320GB448251015	2025-10-15	Addition in class IIa of MDN 0310 EMDN Y2142 acc. to WO-015184



Products covered by this certificate

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of medical devices
MDN 1201	Is	Non-active non-implantable devices for anaesthesia, emergency and intensive care
MDN 1203	Is	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
MDN 1214	Is	General non-active non-implantable devices used in health care and other non-active non implantable devices

For class I medical devices with a measuring function (class Im), the audit of the quality management system was limited to the aspects relating to the conformity of the devices with the metrological requirements.

Category	Class	Medical devices/groups of medical devices
MDN 1201	Im	Non-active non-implantable devices for anaesthesia, emergency and intensive care

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0310	Y2142	INTERPERSONAL COMMUNICATION DEVICES
MDN 1201	R0106	PERCUTANEOUS TRACHEOSTOMY KITS
MDN 1203	R0106	PERCUTANEOUS TRACHEOSTOMY KITS
MDN 1214	R0402	NATURAL BREATHING FILTERS
MDN 1214	R9006	PHONATION VALVES

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN1201	R010501	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
MDN1201	R010502	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
MDN1201	R010503	TRACHEOSTOMY INNER CANNULAS

Intended purpose

FAHL® tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy. The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutan variants are designed for additional use in percutaneous dilatation tracheostomy