

# EU Quality Management System Certificate

Certificate no.  
2026GB448250304

Final Assessment Report no.  
2026AU26F

Effective date  
2025-03-04

Expiry date  
2028-02-02

This is to certify that the quality system of  
**RoweMed AG - Medical 4 Life**  
Juri-Gagarin-Ring 4, 19370 Parchim, Germany  
SRN: DE-MF-000005350

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, 2025-03-04

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

Marcus Harder  
Certification Body

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



**DNV**

Certificate no.: 2026GB448250304  
Place and date: Hamburg, 2025-03-04

**Preceding certificate**

<b>Certificate no.</b>	<b>Issue date</b>	<b>Identification of changes</b>
2026GB448240717	2024-07-17	Extension by MDN 1201 for class IIa (WO-010175)

**Sites covered by this certificate**

RoweMed AG - Medical 4 Life, Juri-Gagarin-Ring 4, 19370 Parchim, Germany





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## 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 1202	Is	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1214	Is	General non-active non-implantable devices used in health care and other non-active non-implantable devices

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1201	A040101	ADMINISTRATION AND ASPIRATION FILTERS
	R010380	ENDOTRACHEAL TUBES - ACCESSORIES
MDN 1202	A030401	INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
	A040101	ADMINISTRATION AND ASPIRATION FILTERS
	A0703	STOPCOCKS
	A060304	INTRA-OPERATION FLUID COLLECTION DEVICES
	B010199	BLOOD COLLECTION BAGS AND KITS — OTHER
	B0180	BLOOD BAGS AND KITS — ACCESSORIES
	C010180	PERIPHERAL I.V. CATHETERS AND CANNULAS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
C010401	CARDIAC ANGIOGRAPHY DEVICES	