

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
3827GB448260128

Final Assessment Report no.
3827AU20F

Effective date
2026-01-28

Expiry date
2027-10-16

This is to certify that the quality system of

Euro Vital Pharma GmbH

Borsteler Chaussee 47, 2453 Hamburg, Germany

SRN: DE-MF-000025194

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, 2026-01-28

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



Lorenz Runge
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.: [3827GB448260128](#)
Place and date: [Hamburg, 2026-01-28](#)

Sites covered by this certificate

Euro Vital Pharma GmbH , Borsteler Chaussee 47, 22453 Hamburg, Germany

Preceding certificate

Certificate no.	Issue date	Identification of changes
3827GB448250203	2025-02-03	Addition of Class IIa MDN 1213 EMDN M0412 acc to WO-010291 and EMDNs M9002, Q030103, Q030199, Q030402, V0999, and V9017



Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	M0412	Dressings for the treatment of warts, corns and calluses
	M9002	Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)
	Q030103	Nasal irrigation solutions
	Q030199	Nasopharyngeal devices - other
	Q030402	Ear irrigation devices
	V0999	Fluids/gases for clinical/therapeutical use - other
	V9017	Oral administration preparations not included in other classes

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	G0401	ORALLY ADMINISTERED DEVICES FOR THE THERAPY OF GASTRO-INTESTINAL DISORDERS

Intended purpose

The medical device is a defoamer and is used to treat flatulence and bloating caused by gas bubbles in the food pulp of the gastrointestinal tract

