



DNV

# EU Quality Management System Certificate

Certificate no.  
3558GB448250410

Final Assessment Report no.  
3558AU23F

Effective date  
2025-04-10

Expiry date  
2026-07-28

This is to certify that the quality system of

**HÄLSA Pharma GmbH**

Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

SRN: DE-MF-000007407

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, 2025-04-10

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.: 3558GB448250410  
Place and date: Hamburg, 2025-04-10

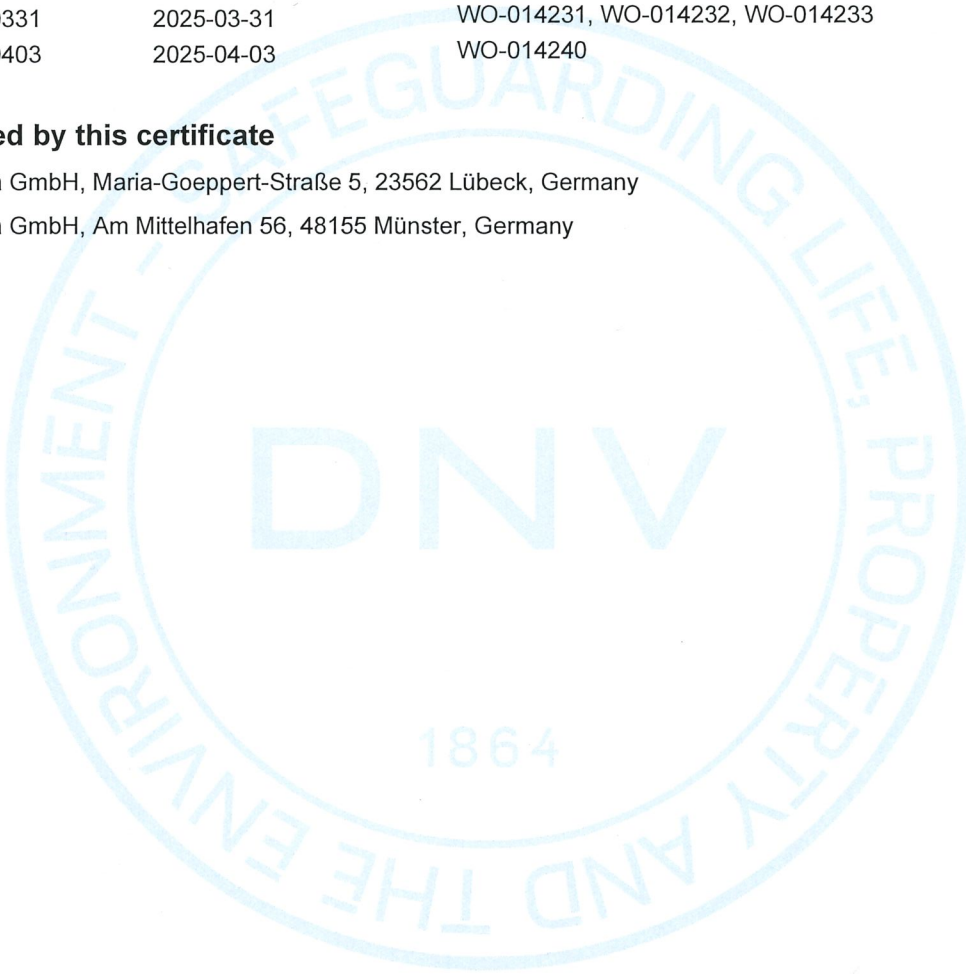
**Preceding certificate**

<b>Certificate no.</b>	<b>Issue date</b>	<b>Identification of changes</b>
3558GB448220714	2022-07-14	WO-009807, Addition of MDN 1213
3558GB448240227	2024-02-27	WO-009830, WO-010350
3558GB448240808	2024-08-08	WO-013551
3558GB448240830	2024-08-30	WO-009797, WO-009817, Correction of Ila Wording/Device Group
3558GB448241008	2024-10-08	WO-012954, WO-009816, WO-010351
3558GB448250304	2024-03-04	WO-010357
3558GB448250331	2025-03-31	WO-014231, WO-014232, WO-014233
3558GB448250403	2025-04-03	WO-014240

**Sites covered by this certificate**

HÄLSA Pharma GmbH, Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

HÄLSA Pharma GmbH, Am Mittelhafen 56, 48155 Münster, Germany





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## Products covered by this certificate

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A99	Devices for administration, withdrawal and collection – other
MDN 1202	R900901	Inhalers
MDN 1204	V9099	Various devices not included in other classes - other
MDN 1213	Q019003	Dental floss and other devices for oral hygiene (for professional use)
MDN 1213	Q030199	Nasopharyngeal devices – other

### Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	Q030199	Nasopharyngeal devices – other

#### Intended purpose

The device is to be used for symptomatic treatment of the common cold, blocked nose and nasal dryness. The device moisturizes, cleanses and nurtures the nasal mucosa and relieves symptoms such as nasal congestion/obstruction, rhinorrhea and nasal crusting.

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 device is intended to be taken orally for the relief of excess gas in the gastrointestinal tract.

#### Intended purpose

The device and all variants is an osmotic laxative developed for the symptomatic treatment of constipation. It is intended for oral use only.

#### Intended purpose

For the symptomatic treatment of gas-related gastrointestinal complaints, e.g. bloating, belching, gas.

### Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1204	Non-active non-implantable devices for wound and skin care
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