EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
3558GB448250804	3558AU23F	2025-08-04	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 & 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, 2025-08-04

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

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

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev. 6 2025.07.16

Certificate no.: 3558GB448250804
Place and date: Hamburg, 2025-08-04

Sites covered by this certificate

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

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

Preceding certificate

Certificate no.	Issue date	Identification of changes
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 IIa 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
3558GB448250410	2025-04-10	WO-014460, WO-014462, WO-014557
3558GB448250721	2025-07-21	Correction of expiry date
3558GB448250723	2025-07-23	WO-010752, WO-014226
3558GB448250730	2025-07-30	Correction Intended Purpose EMDN U0803

Certificate no.: 3558GB448250804
Place and date: Hamburg, 2025-08-04

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A13	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1202	R900901	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1204	V9099	Non-active non-implantable devices for wound and skin
MDN 1213	Q019003	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route
MDN 1213	Q030199	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route

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

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

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

Intended purpose

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

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 used for the symptomatic treatment of gastrointestinal pain and discomfort caused by gas, like flatulence, feeling of fullness, belching, functional dyspepsia, cramping pain in the upper abdomen, postoperative gas pain and irritable bowel syndrome. The medical device is used for the preparation of diagnostic examinations, e.g. radiology, ultrasonography and endoscopy.

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 intended to be used for the relief and symptomatic treatment of gas related gastrointestinal complaints like meteorism, bloating, epigastralgia, eructation, functional dyspepsia, irritable bowel syndrome and post-operative gas-related pain as well as for the preparation of gastrointestinal diagnostics, such as endoscopy, X-ray and sonography

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.

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Place and date: Hamburg, 2025-08-04

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	U0803	VAGINAL DEVICES IN THE FORM OF SOLUTIONS/CREAMS/OVA/TABLETS

Intended purpose

Cream for the treatment of vaginal dryness, where it is expected to moisturize the dry vagina and to alleviate related symptoms such as itching, burning and pain as well as to regenerate and protect the vaginal environment after infections.

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

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