EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
3558GB448260709	3558AU26F	2026-07-29	2031-07-28

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, 2026-06-09

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
Brooktorkai 18, 20457 Hamburg, Germany

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

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

820111 EN Rev 9 2026.03.23

Certificate no.: 3558GB448260709
Place and date: Hamburg, 2026-07-09

Sites covered by this certificate

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

Preceding certificate

Certificate no.	Issue date	Identification of changes
3558GB448220714	2022-07-14	Initial Issue
3558GB448260420	2026-04-20	WO-015375, WO-015042, WO-015512, Renewal

Certificate no.: 3558GB448260709
Place and date: Hamburg, 2026-07-09

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0307	R0680	NEBULISATION AND HUMIDIFICATION SYSTEMS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
MDN 1202	A13	APPLICATORS FOR DRUGS AND MEDICAL DEVICES NOT PRESENT IN OTHER CLASSES
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
MDN 1213	Q030499	OTOLOGY DEVICES - OTHER

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.

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.

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.

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.

Intended purpose

The device is intended for the treatment of gas-related gastrointestinal discomfort, such as bloating, eructation, crampy abdominal pain, feeling of fullness, feeling of pressure and tension.

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	R060203	INHALATION THERAPY HUMIDIFICATION LIQUIDS

Intended purpose

Medical Device is a sterile hypertonic solution of sodium chloride for inhalation. Due to its osmotic effects, it is used for the enhancement of mucus mobilization in the treatment of diseases of the lower airways associated with mucus obstruction such as CF.

Intended purpose

The product is a sterile hypertonic solution of sodium chloride. Due to its osmotic effects, it is used for the increase of mucus mobilisation in the lower airways in diseases that are associated with mucus obstruction, e. g. acute bronchiolitis and acute obstructive bronchitis in infants and toddlers/young children. The product may be used either as monotherapy or in combination with bronchodilators such as adrenaline (epinephrine) or salbutamol, in case that the respective medicinal product is suitable for such a dilution according to the instructions by the manufacturer of the medicinal product. The product is intended for inhalation with an electric nebulizer only.

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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