



DNV

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
3558GB445240905

Final assessment report no.  
3558AU23F

Effective date  
2024-09-05

Expiry date  
2027-07-28

This is to certify that

**HÄLSA Pharma GmbH**

Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

**EN ISO 13485:2016**

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date  
Hamburg, 2024-09-05

For the issuing office  
DNV MEDCERT GmbH  
Pilatuspool 2, 20355 Hamburg, Germany



**Markus Bianchi**  
Director 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

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

820115 EN Rev 2 2024.08.15

ACCREDITED UNIT: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (currently registered as DNV MEDCERT GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

## Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of physically acting products for

- Treatment of
  - Vaginal disorders
  - Chronic wounds
  - Gastro-intestinal disorders
  - Oedematous swellings of the external ear canal accompanied by pain
- Reduction of
  - Elevated blood lipid levels
  - Overweight
- Weight control

Manufacturing and distribution of physically acting products for

- Treatment of
  - Dry eyes
  - Sore throat, dry cough and hoarseness
- Application on mucous membranes
- Topical applications
- Alleviation of haemorrhoidal disorders

Design and development, manufacturing, and distribution of

- Material filters
- Physically acting nasal sprays

Manufacturing and distribution of

- Isotonic NaCl-solutions
- Sterile NaCl-solutions
- Sterile plasters and wound closures

## Sites covered by this certificate and associated (partial) scopes

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

Oversight on all matters related to the management process

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

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- Treatment of
  - Vaginal disorders
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Place and date: Hamburg, 2024-09-05

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