

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
3558GB445240612

Final assessment report no.
3558AU22F

Effective date
2024-06-12

Expiry date
2024-07-28

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, 2024-06-12

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



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


Markus Bianchi
Director Certification Body

Sites covered by this certificate

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

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

Activities and products/services covered by this certificate

Design and development, manufacture, final inspection 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

Manufacture, final inspection 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, manufacture, final inspection, and distribution of

- Material filters
- Physically acting nasal sprays

Manufacture, final inspection and distribution of

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