

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

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

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2022-07-14
Expiry date: 2024-07-28

Report No.: 3558IA18F
Procedure No.: QS – 3558
Certificate No.: 3558GB445220714

Hamburg, 2022-07-14



MEDCERT Certification Body
Lotenz Runge

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
accredited by DAkkS.

Appendix of certificate

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Activities and products/services in the scope of certification

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

Locations in the scope of certification

HÄLSA Pharma GmbH
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This appendix is integral part of the above-referenced certificate.
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