

## 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:

Design and development, manufacture, final inspection, distribution of products as listed in the appendix

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date:

2021-02-05

Expiry date:

2022-07-29

Report No.:

3558FS16F

Procedure No.:

QS - 3558

Certificate No.:

3558GB445210205A

Hamburg, 2021-02-05

MEDCERT Certification Body (Dr. Andreas Schich)

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 DAkkS accredited management systems certification body





## Appendix of certificate

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List of activities and products included in the scope of 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

- End of list -

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

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