

Certificate

The Certification Body

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

herewith confirms 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, manufacture, final inspection and distribution of
Medical devices as per attachment 1**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:


EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 29 July 2022

Report No.: 3558FS16F
Process No.: QS - 3558
Certificate No.: 3558GB445190909A

Hamburg, 09 September 2019


MEDCERT Certification Body
(Lorenz Riunge)

Attachment 1
EN ISO 13485:2016
QS - 3558

This attachment is valid only in connection with certificate No. 3558GB445190909A

Design, manufacture, final inspection and distribution of physically acting products for

- **Treatment of**
 - **Dry eyes**
 - **Vaginal disorders**
 - **Chronic wounds**
 - **Gastro-intestinal disorders**
 - **Oedematous swellings of the external ear canal accompanied by pain**
 - **Sore throat, dry cough and hoarseness**
- **Topical applications**
- **Reduction of**
 - **Elevated blood lipid levels**
 - **Overweight**
- **Weight control**
- **Alleviation of haemorrhoidal disorders**

Design, manufacture, final inspection and distribution of

- **Material filters**
- **Isotonic NaCl-solutions**
- **Sterile NaCl-solutions**
- **Physically acting nasal sprays**

Hamburg, 09 September 2019



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**DAkkS**

Deutsche
Akkreditierungsstelle
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