

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 13485:2012 + AC:2012

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 31 March 2019

Report No.: 3558PS14F
Process No.: QS - 3558
Certificate No.: 3558GB438180322

Hamburg, 22 March 2018



MEDCERT Certification Body
(Dr. Andreas Schich)



Attachment 1
EN ISO 13485:2012 + AC:2012
QS - 3558

This attachment is valid only in connection with certificate No: 3558GB438180322

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**

Hamburg, 22 March 2018



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