

EC Certificate of Conformity

The Notified 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 assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date:

2020-05-19

Expiry date:

2024-05-27

Report No.:

3558FS16F

Process No.:

QS - 3558

Certificate No.:

3558GB414200519

Hamburg, 2020-05-19

MEDCERT Certification Body (Dr. Andreas Schich)

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MEDCERT Identification Number: 0482





Appendix of EC Certificate of Conformity

Process No.:

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List of products / product categories included in the scope of certificate

- Isotonic NaCl-solutions
- Sterile NaCl-solutions
- Physical acting products for the treatment of gastro-intestinal disorders
- Physical acting products for the treatment of topical applications
- Products for the treatment of dry eyes
- Products for the treatment of vaginal disorders
- Products for alleviation of haemorrhoidal disorders
- Products for the treatment of sore throat, dry cough and hoarseness
- Physically acting products for the application on mucous membranes

- End of list -

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