

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 II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

Effective date: 2021-05-21

Expiry date: 2024-05-27

Report No.: 3558PS17F

Process No.: QS – 3558

Certificate No.: 3558GB410210521A

Hamburg, 2021-05-21



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 Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
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Appendix of EC Certificate of Conformity

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List of products / product categories included in the scope of certificate**Physical acting products**

- **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**
- **for weight control**
- **Material filters**
- **Physically acting nasal sprays**

– End of list –

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