

# 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 aspects of manufacture concerned with securing and maintaining sterile conditions**

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: 2021-02-05**


**Expiry date: 2024-05-27**

Report No.: 3558FS16F

Process No.: QS – 3558

Certificate No.: 3558GB415210205A

Hamburg, 2021-02-05

  
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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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Certificate of Conformity

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

- Sterile glucose solution
- Physically acting nasal sprays
- Sterile plasters and wound closures

– End of list –

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