

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 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.

This certificate is valid until 27 May 2024

Report No.: 3558FS16F
Process No.: QS – 3558
Certificate No.: 3558GB415190909

Hamburg, 09 September 2019


MEDCERT Certification Body
(Lorenz Runge)

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 F10010014e EN / Rev. 8 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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

– End of list –

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