



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
3558GB445240905A

Final assessment report no.
3558AU23F

Effective date
2024-09-05

Expiry date
2027-07-28

This is to certify that

HÄLSA Pharma GmbH

Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2024-09-05

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Markus Bianchi
Director Certification Body



Certificate no.: [3558GB445240905A](#)
Place and date: [Hamburg, 2024-09-05](#)

Activities and products/services covered by this certificate

- European Authorized Representative for manufacturers of medical devices

Sites covered by this certificate and associated (partial) scopes

HÄLSA Pharma GmbH, Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

Oversight on all matters related to the management process

HÄLSA Pharma GmbH, Am Mittelhafen 56, 48155 Münster, Germany

European Authorized Representative for manufacturers of medical devices