EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
3558GB448250304	3558AU23F	2024-03-04	2026-07-28

This is to certify that the quality system of

HÄLSA Pharma GmbH

Maria-Goeppert-Straße 5, 23562 Lübeck, Germany

SRN: DE-MF-000007407

For design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-03-04

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Certification Body

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

Certificate no.: 3558GB448250304
Place and date: Hamburg, 2025-03-04

Preceding certificate

Certificate no.	Issue date	Identification of changes
3558GB448220714	2022-07-14	WO-009807, Addition of MDN 1213
3558GB448240227	2024-02-27	WO-009830, WO-010350
3558GB448240808	2024-08-08	WO-013551
3558GB448240830	2024-08-30	WO-009797, WO-009817, Correction of IIa Wording/Device Group
3558GB448241008	2024-10-08	WO-012954, WO-009816, WO-010351

Sites covered by this certificate

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

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

Certificate no.: 3558GB448250304
Place and date: Hamburg, 2025-03-04

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A99	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1202	R900901	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1204	V9099	Non-active non-implantable devices for wound and skin
MDN 1213	Q019003	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route
MDN 1213	Q030199	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route

Class IIb medical devices, excluding implantable non-WET*

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	Q030199	Nasopharyngeal devices - other

[redacted]

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1204	Non-active non-implantable devices for wound and skin care
MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.