MED CERT®

Certification. Medical Only.

EU Quality Management System Certificate

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

SRN DE-MF-000007407

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date:	**2022-07-14**
Expiry date:	**2026-07-28**
Report No.:	3558IA18F
Procedure No.:	QS – 3558
Certificate No.:	3558GB448220714
Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

Hamburg, 2022-07-14

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.

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

MEDCERT Notified Body Identification Number: 0482

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 3558
Certificate No.: 3558GB448220714

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

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