

Dokument

ISO 13485: 2021 (EN), (Engelhard)



ENGELHARD

Dokumenteninformationen

Interne Dokumentennummer	gültig bis
EAQMS-2023-039	18.09.2028
Fragen zum Dokument – Bitte Email an:	Zertifikatsart
quality.management@engelhard.de	ISO-Zertifikat
Änderungsgrund	
Anpassung Geltungsbereich aufgrund interner Vorgaben bei der DQS	
Ggf. zusätzliche Information	

Erläuterung

Es handelt sich hierbei um ein Zertifikat eines Dienstleisters oder von Engelhard Arzneimittel. Die Abteilung QM überwacht die Aktualität des Zertifikats.

Wird das Zertifikat benötigt?

➔ Zertifikate für z.B. Behördenanfragen bitte als Original herunterladen über den Button:





CERTIFICATE



This is to certify that the company

Engelhard Arzneimittel GmbH & Co. KG

Herzbergstraße 3
61138 Niederdorfelden
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Design and development, production and distribution of non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice route and non-active non-implantable devices for wound and skin care.

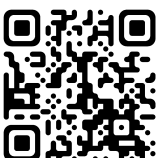
Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485:2021
EN ISO 13485:2016 / A11:2021
ISO 13485:2016

Certificate registration no.	321520 MP2021
Certificate unique ID	1000266114
Effective date	2026-05-28
Expiry date	2028-09-18
Frankfurt am Main	2026-05-28



DQS IS A MEMBER OF



DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany
The validity of the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 321520 MP2021
Certificate unique ID: 1000266114
Effective date: 2026-05-28

Engelhard Arzneimittel GmbH & Co. KG

Herzbergstraße 3
61138 Niederdorfelden
Germany

Location

Scope

550349

Engelhard Arzneimittel GmbH & Co. KG

Herzbergstraße 3
61138 Niederdorfelden
Germany

Design and development, production and distribution of non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice route and non-active non-implantable devices for wound and skin care.

549592

Engelhard Arzneimittel GmbH

Am Magna Park 9
35510 Butzbach
Germany

Storage of non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice route and non-active non-implantable devices for wound and skin care.