



# 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:

Development, production, control, storage and distribution of medical devices for application in case of irritations of the respiratory tract and for wound 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	1000265649
Effective date	2025-09-19
Expiry date	2028-09-18
Frankfurt am Main	2025-09-18



DQS IS A MEMBER OF



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [info-med@dqs.de](mailto:info-med@dqs.de)  
The validity of the certification can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 321520 MP2021**  
**Certificate unique ID: 1000265649**  
**Effective date: 2025-09-19**

## **Engelhard Arzneimittel GmbH & Co. KG**

Herzbergstraße 3  
61138 Niederdorfelden  
Germany

### **Location**

### **Scope**

#### **550349**

**Engelhard Arzneimittel GmbH & Co. KG**  
Herzbergstraße 3  
61138 Niederdorfelden  
Germany

Development, production, control, storage and distribution of medical devices for application in case of irritations of the respiratory tract and for wound care.

#### **549592**

**Engelhard Arzneimittel GmbH**  
Am Magna Park 9  
35510 Butzbach  
Germany

Storage of medical devices for application in case of irritations of the respiratory tract and for wound care.