



CERTIFICATE



This is to certify that the company

Rommelag CDMO GmbH

Bahnhofstraße 18
74429 Sulzbach-Laufen
Germany

with the organizational units/sites as listed in the annex

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

Scope:

Contract manufacturing of sterile or aseptically filled, liquid and semi-solid non-active, non-implantable and implantable medical devices using the bottelpack®-aseptic system.

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 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

Certificate registration no.	393055 MP2016
Certificate unique ID	1000260865
Effective date	2025-08-19
Expiry date	2026-04-14
Frankfurt am Main	2025-08-19



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
The validity of the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 393055 MP2016
Certificate unique ID: 1000260865
Effective date: 2025-08-19

Rommelag CDMO GmbH

Bahnhofstraße 18
74429 Sulzbach-Laufen
Germany

Location

Scope

516389

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74429 Sulzbach-Laufen
Germany

Contract manufacturing of sterile or aseptically filled, liquid and semi-solid non-active, non-implantable and implantable medical devices using the bottelpack®-aseptic system.

393052

Rommelag CDMO GmbH

Bahnhofstraße 20
73453 Abtsgmünd-Untergröningen
Germany

Contract manufacturing of sterile or aseptically filled, liquid and semi-solid non-active, non-implantable and implantable medical devices using the bottelpack®-aseptic system.