



CERTIFICATE



This is to certify that the company

Rommelag CDMO GmbH

Lohnherstellung und -verpackung nach dem bottelpack®-Aseptik System

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	1000238838
Effective date	2025-05-26
Expiry date	2026-04-14
Frankfurt am Main	2025-05-26



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: 1000238838
Effective date: 2025-05-26

Rommelag CDMO GmbH

Lohnherstellung und -verpackung nach dem bottelpack®-Aseptik System

Bahnhofstraße 18
74429 Sulzbach-Laufen
Germany

Location

Scope

516389

Rommelag CDMO GmbH
Werk 1: Lohnherstellung und -verpackung
nach dem bottelpack®-Aseptik System

Bahnhofstraße 18
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
Werk 2: Lohnherstellung und -verpackung
nach dem bottelpack®-Aseptik System

Bahnhofstraße 20
73453 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.