CERTIFICATE

This is to certify that the company

gerresheimer

Gerresheimer Regensburg GmbH

Kumpfmühler Str. 2
93047 Regensburg
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System** for
primary packaging materials for medicinal products – particular requirements for the application of ISO 9001:2015, with reference to Good Manufacturing Practice (GMP)

Scope:
Design and development, production, distribution, trade and sales of primary packaging material and application systems as primary packaging material for medicinal products made of plastics and tubular glass as well as injection molds and automation systems for the manufacturing of primary packaging material.

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 15378 : 2018-04
ISO 15378 : 2017
EN ISO 15378 : 2017

Certificate registration no.	000450 PPM17
Certificate unique ID	1000197947
Effective date	2025-01-18
Expiry date	2027-06-03
Frankfurt am Main	2025-01-18

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

DQS IS A MEMBER OF
IQNET

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.

402.02 Version 4.0

Annex to certificate
Certificate registration No.: 000450 PPM17
Certificate unique ID: 1000197947
Effective date: 2025-01-18

Gerresheimer Regensburg GmbH

Kumpfmühler Str. 2
93047 Regensburg
Germany

Location	Scope
001848 **Gerresheimer Bünde GmbH** Erich-Martens-Str. 26-32 32257 Bünde Germany	Design and Development, production, distribution, trade and sales of primary packaging material and application systems as primary packaging material for medicinal products made of plastics and tubular glass.
060412 **Gerresheimer Regensburg GmbH** Hirtenstraße 50 92536 Pfreimd Germany	Production and distribution of primary packaging material and application systems as primary packaging material for medicinal products made of plastics.
416519 **Gerresheimer Regensburg GmbH** **Technical Competence Center** Oskar-von-Miller-Str. 6 92442 Wackersdorf Germany	Design and development, production, distribution, trade and sales of primary packaging material and application systems as primary packaging material for medicinal products made of plastics and tubular glass as well as injection molds and automation systems for the manufacturing of primary packaging material.
546573 **Gerresheimer Skopje DOOEL Ilinden** Technological Industrial Development Zone Skopje 2 Block 2, Street No. 102, Bunardzik 1041 Municipality of Ilinden 1000 Skopje North Macedonia	Production and distribution of primary packaging material and application systems as primary packaging material for medicinal products made of tubular glass.