CERTIFICATE

This is to certify that

gerresheimer

Gerresheimer Regensburg GmbH

Medical Systems

Kumpfmühler Str. 2
93047 Regensburg
Germany

with the organizational units/sites as listed in the annex

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

Scope:

Design and development, production, trade, distribution and sales of medical devices and primary packaging material, for drugs and medical products, made of plastics and tubular glass as well as injection molds and automation systems.

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

ISO 9001 : 2015

Certificate registration no.	000450 QM15
Date of revision	2025-10-01
Date of certification	2024-06-04
Valid until	2027-06-04

DAkkS Deutsche Akkreditierungsstelle D-ZM-16074-01-00

DQS GmbH

Guido Eggers
Managing Director

DQS IS A MEMBER OF IQNET

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
The validity of the certification can only be verified by the QR-code.

Annex to certificate
Registration no.: 000450 QM15

Gerresheimer Regensburg GmbH

Medical Systems

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Location	Scope
060415 **Gerresheimer Werkzeugbau Wackersdorf GmbH** Oskar-von-Miller-Straße 4 92442 Wackersdorf Germany	Production of molds for the production of medical devices and primary packaging material for drugs and medicinal products made of plastics.
546573 **Gerresheimer Skopje DOOEL Ilinden** Technological Industrial Development Zone Skopje 2, Block 2, Street No. 102, Bunardzik 1041 Municipality of Ilinden 1000 Skopje Republic of North Macedonia	Production and distribution of medical devices and primary packaging material for drugs and 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 and sales of medical devices and primary packaging material for drugs and medicinal products made of plastics and tubular glass as well as injection molds and automation systems.
375119 **Gerresheimer Medical Plastic Systems Dongguan Co., Ltd.** No. 5 Wangniudun Huiyuan Road, Town of Wangniudun 523200 Dongguan City, Guangdong Provi China	Production, distribution and sales of medical devices and primary packaging material for drugs and medicinal products made of plastics as well as design and development and trade of injection molds and automation systems.

This annex (edition: 2025-10-01) is only valid in connection with the above-mentioned certificate.

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Location	Scope
066653 **Gerresheimer Peachtree City L.P.** 650 Highway 74 South Peachtree City, Georgia, 30269 United States of America	Design and development, production, distribution and sales of medical devices and primary packaging material for drugs and medicinal products made of plastics as well as design and development of injection molds and automation systems.
001848 **Gerresheimer Bünde GmbH** Erich-Martens-Str. 26-32 32257 Bünde Germany	Design and development, production, trade, distribution and sales of medical devices and primary packaging material for drugs and medicinal products made of plastics and tubular glass.
292454 **Gerresheimer Horsovsky Tyn spol. s r.o.** Zahradní 282 34601 Horšovský Týn Czech Republic	Production and distribution of medical devices and primary packaging material for drugs and medicinal products made of plastics.
060412 **Gerresheimer Regensburg GmbH** Hirtenstraße 50 92536 Pfreimd Germany	Production and distribution of medical devices and primary packaging material for drugs and medicinal products made of plastics.
543864 **Gerresheimer Regensburg GmbH** Kumpfmühler Str. 2 93047 Regensburg Germany	Design and development, production, trade, distribution and sales of medical devices and primary packaging material, for drugs and medicinal products, made of plastics and tubular glass as well as injection molds and automation systems.

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93047 Regensburg
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Location	Scope
486954 **Gerresheimer Sistemas Plásticos Medicinais São Paulo Ltda.** Rua Victório Emmanuel Soliani, 190 Distrito Industrial Domingos Giomi Indaiatuba, São Paulo 13347-380 Brazil	Production and distribution of medical devices and primary packaging material for drugs and medicinal products made of plastics.

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