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**.

Scope:
Design and Development, development services and production of general non-active and active, non-implantable medical devices made of plastic and tubular glass.

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.	000450 MP2021
Certificate unique ID	1000212000
Effective date	2025-07-21
Expiry date	2027-06-03
Frankfurt am Main	2025-07-21

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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
Administrative Office: DQS AP Ltd.,906-907, Waterfront Place Block E, No.31,Lane 168, Daduhe Road, Putuo District, Shanghai, China, Post Code: 200062
This certificate can be verified at: www.mydqs.com/en/customers/customer-database.html
as well as CNCA official website: www.cnca.gov.cn
Die Gültigkeit von diesem Zertifikat kann nur durch den QR-Code verifiziert werden

414.91e Version 5.0

Annex to certificate
Certificate registration No.: 000450 MP2021
Certificate unique ID: 1000212000
Effective date: 2025-07-21

Gerresheimer Regensburg GmbH

Kumpfmühler Str. 2
93047 Regensburg
Germany

Location	Scope
060412 **Gerresheimer Regensburg GmbH** Hirtenstraße 50 92536 Pfreimd Germany	Production of general non-active and active, non-implantable medical devices made of plastic.
543864 **Gerresheimer Regensburg GmbH** Kumpfmühler Str. 2 93047 Regensburg Germany	Design and Development, development services and production of general non-active and active, non-implantable medical devices made of plastic and tubular glass.
416519 **Gerresheimer Regensburg GmbH Technical Competence Center** Oskar-von-Miller-Str. 6 92442 Wackersdorf Germany	Design and Development, development services and production of general non-active and active, non-implantable medical devices made of plastic and tubular glass.
066653 **Gerresheimer Peachtree City L.P.** 650 Highway 74 South Peachtree City, Georgia, 30269 United States of America	Design and Development, development services and production of general non-active and active, non-implantable medical devices made of plastic.
486954 **Gerresheimer Sistemas Plásticos Medicinais São Paulo Ltda.** Rua Victório Emmanuel Soliani, 190 Distrito Industrial Domingos Giomi Indaiatuba, São Paulo 13347-380 Brazil	Production of general non-active and active, non-implantable medical devices made of plastic.

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Gerresheimer Regensburg GmbH

Kumpfmühler Str. 2
93047 Regensburg
Germany

Location	Scope
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 of general non-active and active, non-implantable medical devices made of plastic and tubular glass.
001848 **Gerresheimer Bünde GmbH** Erich-Martens-Str. 26-32 32257 Bünde Germany	Design and Development, development services and production of general non-active and active, non-implantable medical devices made of plastic and tubular glass.
375119 **Gerresheimer Medical Plastic Systems Dongguan Co., Ltd.** No. 5 Wangniudun Huiyuan Road, Town of WanNiuDun 523200 Dongguan City China	Development services and production of general non-active and active, non-implantable medical devices made of plastic.
292454 **Gerresheimer Horsovsky Tyn spol. s r.o.** Zahradní 282 34601 Horšovský Týn Czech Republic	Production of general non-active and active, non-implantable medical devices made of plastic.