



CERTIFICATE



This is to certify that the company

gerresheimer

Gerresheimer Regensburg GmbH

Medical System

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 and development services, production and sales of general non-active and active medical devices made of plastic and 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 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	000450 MP2016
Certificate unique ID	170781965
Effective date	2022-10-25
Expiry date	2024-06-03
Frankfurt am Main	2022-10-25



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.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

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

DQS IS A MEMBER OF





Annex to certificate
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Gerresheimer Regensburg GmbH

Medical System

Kumpfmühler Str. 2
93047 Regensburg
Germany

Location

Scope

543864

Gerresheimer Regensburg GmbH
Kumpfmühler Str. 2
93047 Regensburg
Germany

Design and Development and development services, production and sales of general non-active and active medical devices made of plastic and glass.

001848

Gerresheimer Bünde GmbH
Erich-Martens-Str. 26-32
32257 Bünde
Germany

Design and Development and development services, production and sales of general non-active and active medical devices made of plastic and glass.

060412

Gerresheimer Regensburg GmbH
Hirtenstraße 50
92536 Pfreimd
Germany

Production and distribution of general non-active and active medical devices made of plastics.

066653

Gerresheimer Peachtree City L.P.
650 Highway 74 South
Peachtree City, Georgia, 30269
United States of America

Design and Development and development services, production and sales of general non-active and active medical devices made of plastic.

292454

Gerresheimer Horšovský Týn spol. s r.o.
Zahradní 282
34601 Horšovský Týn
Czech Republic

Production and distribution of general non-active and active medical devices made of plastics.



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Gerresheimer Regensburg GmbH

Medical System

Kumpfmühler Str. 2
93047 Regensburg
Germany

Location

Scope

375119

**Gerresheimer Medical Plastic Systems
Dongguan Co., Ltd.**

Building 5 - 6, Zone No. 4, ZhongHanQiao
Industrial Park, WanNiuDun Town
523200 Dongguan City, Guangdong Provi
China

Development services, production and sales of
general non-active and active medical devices
made of plastic.

416519

**Gerresheimer Regensburg GmbH
Technical Competence Center**

Oskar-von-Miller-Str. 6
92442 Wackersdorf
Germany

Design and Development and development
services, production and sales of general non-
active and active medical devices made of
plastic and glass.

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 general non-
active and active medical devices 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
Mazedonien

Production and distribution of general non-
active and active medical devices made of
plastics.