



# CERTIFICATE



This is to certify that the company

**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 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 : 2018**  
**ISO 13485 : 2016**

Certificate registration no.	000450 MP2016
Certificate unique ID	1000158577
Effective date	2024-06-04
Expiry date	2027-06-03
Frankfurt am Main	2024-06-03



**DQS Medizinprodukte GmbH**

Sigrid Uhlemann  
Managing Director

Szymon Kurdyn  
Product Manager

DQS IS A MEMBER OF



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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](http://www.mydqs.com/en/customers/customer-database.html)  
as well as CNCA official website: [www.cnca.gov.cn](http://www.cnca.gov.cn)

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



**Annex to certificate**  
**Certificate registration No.: 000450 MP2016**  
**Certificate unique ID: 1000158577**  
**Effective date: 2024-06-04**

## **Gerresheimer Regensburg GmbH**

Medical Systems

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  
Republic of North Macedonia

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

#### **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.

#### **375119**

**Gerresheimer Medical Plastic Systems**  
**Dongguan Co., Ltd.**  
Building 5 - 6, Zone No. 4,  
ZhongHanQiao Industrial Park,  
WanNiuDun Town  
523200 Dongguan City  
China

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

#### **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.



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## **Gerresheimer Regensburg GmbH**

Medical Systems

Kumpfmühler Str. 2  
93047 Regensburg  
Germany

### **Location**

### **Scope**

#### **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.

#### **292454**

**Gerresheimer Horsovsky Tyn 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.

#### **060412**

**Gerresheimer Regensburg GmbH**  
Hirtenstraße 50  
92536 Pfreimd  
Germany

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

#### **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.

#### **486954**

**Gerresheimer Sistemas Plásticos Mediciniais 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.