



# 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** 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, 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

000450 PPM17

170773961

2021-06-04

2024-06-03

2021-06-02

Certificate registration no.

Certificate unique ID

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Effective date

Expiry date

Frankfurt am Main

#### **DQS Medizinprodukte GmbH**

16 lu

Sigrid Uhlemann Managing Director

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

Hovsep Aro Product Manager



August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, <u>medical.devices@dqs-med.de</u>





Annex to certificate Certificate registration No.: 000450 PPM17 Certificate unique ID: 170773961 Effective date: 2021-06-04

## **Gerresheimer Regensburg GmbH**

Medical System Kumpfmühler Str. 2 93047 Regensburg Germany

Location

**Gerresheimer Regensburg GmbH** Kumpfmühler Str. 2 93047 Regensburg Germany

#### 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.

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

### Gerresheimer Regensburg GmbH

Hirtenstraße 50 92536 Pfreimd Germany

Gerresheimer Regensburg GmbH Oskar-von-Miller-Str. 6

92442 Wackersdorf Germany Production and distribution of primary packaging material and application systems as primary packaging material for medicinal products made of plastics.

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.

