



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** for primary packaging materials for medicinal products – particular requirements for the application of ISO 9001:2008, 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:

ISO 15378 : 2015

Certificate registration no. 000450 PPM15

Certificate unique ID 170708593
Effective date 2018-06-04

Effective date 2010-00-04

Expiry date 2021-06-03

Frankfurt am Main 2018-06-04

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director

Wlew

Markus Ruppel Product Manager







Annex to certificate

Certificate registration No.: 000450 PPM15

Certificate unique ID: 170708593

Effective date: 2018-06-04

Gerresheimer Regensburg GmbH

Medizinische Kunststoffsysteme

Kumpfmühler Str. 2 93047 Regensburg Germany

001848

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.

060412

Gerresheimer Regensburg GmbH Medizinische Kunststoffsysteme

Hirtenstraße 50 92536 Pfreimd Germany Production and distribution of primary packaging material and application systems as primary packaging material for 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, 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.

508180

Gerresheimer item GmbH

Am Mittelhafen 10 48155 Münster Germany Design and development of primary packaging material and application systems as primary packaging material for medicinal products made of plastics and tubular glass.

