ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010283 0640 Rev. 02

Holder of Certificate: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, Systems, Instruments, Software and Consumables) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/ Immunohematology, Microbiology, Infectious Immunology, Histology/Cytology and Genetic Testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 010283 0640 Rev. 02

Report No.: 713317344

Valid from: 2024-06-30
Valid until: 2027-06-29

Date, 2024-04-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Roche Diagnostics GmbH
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Design and Development, and Manufacture of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, Systems, Instruments, and Consumables) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/Immunohematology, Microbiology, Infectious Immunology, Histology/Cytology and Genetic Testing

Distribution of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, Systems, Instruments, Software and Consumables) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/Immunohematology, Microbiology, Infectious Immunology, Histology/Cytology and Genetic Testing

Roche Diagnostics GmbH
Nonnenwald 2, 82377 Penzberg, GERMANY

Design and Development of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, and Consumables) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/Immunohematology, Microbiology and Infectious Immunology

Manufacture of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/Immunohematology, Microbiology and Infectious Immunology

Roche Diagnostics International Ltd
Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND

Design and Development of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, Systems, Instruments, Software and Consumables) used in the areas of clinical chemistry, immunochemistry, Haematology/Haemostasis/Immunohematology, Microbiology, Infectious Immunology and Histology/Cytology

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No. Q5 010283 0640 Rev. 02

Roche mtm laboratories AG
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Design and Development of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, and Consumables) used in the areas of Histology/Cytology

Manufacture of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, and Consumables) used in the areas of Histology/Cytology

Roche Diagnostics GmbH
Staffelseestraße 4, 81477 München, GERMANY

Design and Development of In-Vitro Diagnostic Medical Devices (Reagents and Reagent Products, and Consumables) used in the areas of clinical chemistry

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