



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



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](http://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

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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