CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

Certificate

No. Q5 051951 0018 Rev. 06

Holder of Certificate: **Roche Diagnostics International Ltd**
Forrenstrasse 2
6343 Rotkreuz
SWITZERLAND

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, Infectious Immunology, 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 051951 0018 Rev. 06

Report No.: 713386302

Valid from: 2026-07-01
Valid until: 2029-06-30

Date, 2026-05-27

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 International Ltd
Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND

See Scope of Certificate.

Roche Diagnostics SL
Avinguda de la Generalitat 171-173, Sant Cugat del Vallès, 08174 Barcelona, SPAIN

Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Software used in the areas of Clinical Chemistry, Immunochemistry, Haematology/Haemostasis/Immunohematology, Infectious Immunology, and Genetic Testing
Design and Development of Reagents for In-Vitro Diagnostic Systems used for Haematology/Haemostasis/Immunohematology

Roche Diagnostics Automation Solutions GmbH
Albert-Ruprecht-Strasse 2, 71636 Ludwigsburg, GERMANY

Design and Development, Manufacture and Distribution of Laboratory Instruments and Software for In-Vitro Diagnostic Systems used in the areas of Clinical Chemistry, Immunochemistry, Haematology/Haemostasis/Immunohematology, Infectious Immunology, and Genetic Testing

Roche Information Solutions India Pvt. Ltd.
Tower B, 45ICON, Baner, Pune 411 045, INDIA

Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Software used in the areas of Clinical Chemistry, Immunochemistry, Haematology/Haemostasis/Immunohematology, Infectious Immunology, and Genetic Testing

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