



Product Service

Certificate

No. Q5 053046 0038 Rev. 04

Holder of Certificate: **FUJIFILM Wako Pure Chemical Corporation**
1-2, Doshomachi 3-Chome, Chuo-ku
Osaka
540-8605 JAPAN

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In-Vitro Diagnostic (IVD) Reagents, Calibrators and Controls for Clinical Chemistry, Immunology, Microbiology and Hematology**
Design and Development, Production, Distribution, Installation and Servicing of IVD Instruments for Clinical Chemistry, Immunology and Microbiology

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 053046 0038 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_053046_0038_Rev._04)

Report No.: JV200350009642

Valid from: 2025-07-28

Valid until: 2027-10-16

Date, 2025-07-28

Christoph Dicks
Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



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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): **FUJIFILM Wako Pure Chemical Corporation**
1-2, Doshomachi 3-Chome, Chuo-ku, Osaka, 540-8605 JAPAN

Management of In-Vitro Diagnostic (IVD) Reagents, Calibrators
and Controls for Clinical Chemistry, Immunology, Microbiology and
Hematology
Management of IVD Instruments for Clinical Chemistry,
Immunology and Microbiology

**FUJIFILM Wako Pure Chemical Corporation Osaka
Plant**
6-1, Takata-cho, Amagasaki-shi, Hyogo, 661-0963 JAPAN

Design and Development, Production and Distribution of In-Vitro
Diagnostic (IVD) Reagents, Calibrators and Controls for Clinical
Chemistry, Immunology, Microbiology and Hematology

**FUJIFILM Wako Pure Chemical Corporation BMS
Center**
**3-5, Higashikagaya 1-Chome, Suminoe-ku, Osaka, 559-0012
JAPAN**

Design and Development, Production, Distribution, Installation and
Servicing of IVD Instruments for Clinical Chemistry and
Microbiology
Installation and Servicing of IVD Instruments for Immunology

**FUJIFILM Wako Pure Chemical Corporation East
Annex**
3-8, Doshomachi 2-Chome, Chuo-ku, Osaka, 540-8605 JAPAN

Design and Development, and Distribution of In-Vitro Diagnostic
(IVD) Reagents, Calibrators and Controls for Clinical Chemistry,
Immunology, Microbiology and Hematology
Design and Development, Distribution, Installation and Servicing of
IVD Instruments for Clinical Chemistry, Immunology and
Microbiology

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