



Certificate

No. Q5 053046 0038 Rev. 01

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 - Biochemical Reagents, Immunological Reagents, Microbiological Reagents, Hematological Reagents and related Calibrators and Control Design and Development, Production and Distribution, Installation and Servicing of IVD Instruments**

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 and certification regulation of 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. 01

Report No.: **JN1648895**

Valid from: **2021-10-17**
Valid until: **2024-10-16**

Date, **2021-10-13**

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, and Distribution of In-Vitro Diagnostic (IVD)
Reagents - Biochemical Reagents, Immunological Reagents,
Microbiological Reagents, Hematological Reagents and related
Calibrators and Control
Design and Development, Distribution, Installation and Servicing of IVD
Instruments

FUJIFILM Wako Pure Chemical Corporation Mie Plant
2613-2, Oaza Ogohara, Komono-cho, Mie-gun, Mie, 510-1222 JAPAN

Production and Distribution of In-Vitro Diagnostic (IVD) Reagents -
Biochemical Reagents, Immunological Reagents, Microbiological
Reagents, Hematological Reagents and related Calibrators and Control

FUJIFILM Wako Pure Chemical Corporation Mie Komono Plant
4923-12, Oaza Chikusa, Komono-cho, Mie-gun, Mie, 510-1251 JAPAN

Production and Distribution of In-Vitro Diagnostic (IVD) Reagents -
Immunological Reagents, Microbiological Reagents and related
Calibrators and Control

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 - Biochemical Reagents, Immunological
Reagents, Microbiological Reagents, Hematological Reagents and related
Calibrators and Control

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

Design and Development, Production of IVD Instruments

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 - Biochemical Reagents, Immunological Reagents,
Microbiological Reagents, Hematological Reagents and related
Calibrators and Control
Design and Development, Distribution, Installation and Servicing of IVD
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