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MDSAP
Medical Device Single Audit Program

C E R T I F I C A T E

No. QS6 053046 0039 Rev. 07

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

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders; Design and Development, Manufacture, Distribution, Installation and Servicing of IVD Instruments used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 053046 0039 Rev. 07
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001668**
Report No.: **JV200350016532**
Effective Date: **2026-07-22**
Expiry Date: **2027-11-13**

Date of Issue: 2026-08-04

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

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

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

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

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

Date of Issue: 2026-08-04

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TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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No. QS6 053046 0039 Rev. 07

Facility Scopes:

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

Management of IVD Instruments, In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders; Purchasing Control of In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders

REPs Facility ID: F001668

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 Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders; Design and Development, Distribution, Installation and Servicing of IVD Instruments used in the Risk Assessment of Cancer, in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers and Endocrine Disorders

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C E R T I F I C A T E

No. QS6 053046 0039 Rev. 07

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

Manufacture and Distribution of In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Diagnosis and Management of Disease Status and Protein Metabolism; Design and Development of In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders; Distribution of In-Vitro Diagnostic Reagents and related Calibrators and Controls used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders

REPs Facility ID: F002352

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

Design and Development, Manufacture, Installation and Servicing of IVD Instruments used in the Risk Assessment of Cancer, in Blood Banking and in the Diagnosis and Management of Immune Status, Disease Status, Infectious Status, Cardiac Markers, Protein Metabolism, and Endocrine Disorders

REPs Facility ID: F002351

Date of Issue: 2026-08-04

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS

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