



America

CERTIFICATE

No. QS1 16 08 53046 026

Certificate Holder: Wako Pure Chemical Industries, Ltd.
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

Standard(s): ISO 13485:2003

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M3048

Effective Date: 2016-08-01
Expiry Date: 2018-12-31

Gary Minks
Vice President, Regulatory Affairs



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TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
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Design and Development, Manufacture, Distribution, Installation and Servicing of IVD Instruments

Wako Pure Chemical Industries, Ltd.
Mie Plant
2613-2, Oaza Ogohara, Komono-cho
Mie-gun, Mie
510-1222 Japan

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

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No. QS1 16 08 53046 026

BS Wako
6-1, Takada-cho, Amagasaki-shi
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661-0963 Japan

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

Wako Pure Chemical Industries, Ltd.
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1-3-5, Higashikagaya, Suminoe-ku
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559-0012 Japan

Design and Development, Manufacture of IVD Instruments

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