



America

CERTIFICATE

No. QS6 083208 0037 Rev. 00

Certificate Holder: Fujirebio Inc.
2-1-1 Nishishinjuku
Shinjuku-ku, Tokyo
163-0410 JAPAN

Certification Mark:



Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Health Canada, USA FDA, MHLW / PMDA.
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. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

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DUNS No: 71-087-3907

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(Arie Henkin)
Manager, Certification Body MHS

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No. QS6 083208 0037 Rev. 00

Fujirebio Inc. Sagamihara Facility

1-3-14, Tanashioda, Chuo-ku, Sagamihara-shi, Kanagawa, 252-0245
JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Blood Components, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, and Protein Metabolism

DUNS No: 69-312-0142

Fujirebio Inc. Distribution Center

1-17-19, Haijima-cho, Akishima-shi, Tokyo, 196-0002, JAPAN

Distribution of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Genetic Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Distribution In-Vitro Diagnostic Medical Devices, Sampling Tips and Specimen Container used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Genetic Testing, Immune Status, Protein Metabolism, and Transmissible Agents

DUNS No: 69-971-9121



(Arie Henkin)
Manager, Certification Body MHS

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