





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

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

71-087-3907

Effective Date:

2019-03-05

Expiry Date:

2022-03-04

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Date of Issue: 2019-03-18

(Arie Henkin)

Manager, Certification Body MHS

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Regulatory Requirements:

Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002

- Schedule 3, Part 1

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803

- 21 CFR Part 806

- 21 CFR Part 807

- 21 CFR Part 820

Japar

- MHLW Ministerial Ordinance 169, Article 4 to Article 68

- PMD Act

Overall Scope Statement:

Design and Development, Manufacture, and 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: Design, Distribution, Installation, and Servicing of 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

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Facility(ies):

Fujirebio Inc.

2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN

Fujirebio Inc. Hachioji Facility

51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Fujirebio Inc. Hachioji 2nd Facility

153, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Fujirebio Inc. Hachioji 3rd Facility

935, Ishikawa-machi, Hachioji-shi, Tokyo, 192-0032 JAPAN

Fujirebio Inc. Obihiro Facility

8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun,

Hokkaido, 080-0341 JAPAN

Fujirebio Inc. Ube Facility

203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi,

759-0134 JAPAN

Fujirebio Inc. Sagamihara Facility

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

0245 JAPAN

Fujirebio Inc. Distribution Center

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

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Facility Scopes:

Fujirebio Inc.

2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410, JAPAN

Design and Development, and 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; Design, Distribution, Installation, and Servicing of 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: 71-087-3907

Fujirebio Inc. Hachioji FacIlity

51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031, JAPAN

Design and Development, and Manufacture 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, Disease Status, Endocrine Disorders, Fertility Testing, Genetic Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Design and Installation of 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, and Protein Metabolism DUNS No: 70-630-0746

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Fujirebio Inc. Hachioji 2nd Facility 153, Komiya-machi, Hachioji-shi, Tokyo, 192-0031, JAPAN

Manufacture of In-Vitro Diagnostic Reagents used in the Diagnosis, Management, and Detection of Blood Components, Cancer, and Endocrine Disorders
DUNS No: 70-630-0746

Fujirebio Inc. Hachioji 3rd Facility 935, Ishikawa-machi, Hachioji-shi, Tokyo, 192-0032, JAPAN

Manufacture of In-Vitro Diagnostic Reagents used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Coagulation, Endocrine Disorders, Immune Status, and Transmissible Agents
DUNS No: 71-364-1264

Fujirebio Inc. Obihiro Facility 8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun, Hokkaido, 080-0341, JAPAN

Design and Development, and Manufacture of In-Vitro Diagnostic Reagents 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: 70-630-0761

Fujirebio Inc. Ube Facility 203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi, 759-0134, JAPAN

Design and Development, and Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution 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: 70-630-0753

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Fujirebio Inc. Sagamlhara 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

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