



Certificate

No. Q5 083208 0032 Rev. 04

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

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Reagents (Including 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, Immune Status, Protein Metabolism, and Transmissible Agents;
Design and Development, Distribution, Installation, and Servicing of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Makers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents.
Design and Development and Distribution of In-Vitro Diagnostic generic use consumables (Sampling Tips and Specimen Container) for Sample collection, Sample transport and Sample analyses.

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 083208 0032 Rev. 04

Report No.: JN1877718_CN

Valid from: 2022-12-06
Valid until: 2024-09-05

Date, 2022-12-06

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): **Fujirebio Inc.**
2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN

Design and Development and Distribution of In-Vitro Diagnostic Reagents (Including 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, Immune Status, Protein Metabolism, and Transmissible Agents;
Distribution of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents.
Distribution of In-Vitro Diagnostic generic use consumables (Sampling Tips and Specimen Container) for Sample collection, Sample transport and Sample analyses.

Fujirebio Inc. Hachioji Facility
51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Reagents (Including 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, Immune Status, Protein Metabolism, and Transmissible Agents;
Design and Development, Distribution, Installation, and Servicing of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents.
Design and Development and Distribution of In-Vitro Diagnostic generic use consumables (Sampling Tips and Specimen Container) for Sample collection, Sample transport and Sample analyses.

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Facility(ies):

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

Manufacture of In-Vitro Diagnostic Reagents (Including Substrate Solution, Wash Solution, Specimen Diluent and Control) used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Coagulation, Endocrine Disorders, Immune Status, and Transmissible Agents.

Fujirebio Inc. Sagamihara Facility
1-3-14, Tanashioda, Chuo-ku, Sagamihara-shi, Kanagawa, 252-0245 JAPAN

Manufacture of In-Vitro Diagnostic Reagents (Including 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.

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

Manufacture of In-Vitro Diagnostic Reagents (Including 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.

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

Manufacture of In-Vitro Diagnostic Reagents (Including 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.

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Facility(ies):

Fujirebio Inc. Atsugi-Aikawa Distribution Center
4036-1, Nakatsu, Aikawa-cho, Aiko-gun, Kanagawa,
243-0303, JAPAN

Distribution of In-Vitro Diagnostic Reagents (Including 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, Immune Status, Protein Metabolism, and Transmissible Agents;
Distribution of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents.
Distribution of In-Vitro Diagnostic generic use consumables (Sampling Tips and Specimen Container) for Sample collection, Sample transport and Sample analyses.

Fujirebio Inc. Asahikawa Facility
23-1975-167, Minamiyonjodori, Asahikawashi, Hokkaido,
078-8334 JAPAN

Manufacture of In-Vitro Diagnostic Reagents (Including 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.

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