



Certificate

No. Q5 083208 0032 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Nucleic Acid Test Reagent Kits and Accessories**
Design, Distribution, Installation and Servicing of Instruments for Immunoassay and Accessories

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). See also notes overleaf.

Report No.: JNQ235033984

Valid from: 2018-09-06
Valid until: 2021-09-05

Date, 2018-09-06

Stefan Preiß

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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. Shinagawa Facility
4-1-8, Kounan, Minato-ku, Tokyo, 108-0075 JAPAN
 - Fujirebio Inc. Kuki Distribution Center
1662, Shimohayami, Kuki-shi, Saltama, 346-0022 JAPAN
 - Fujirebio Inc. Hachioji Facility
51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN
 - Fujirebio Inc. Ube Facility
203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi,
759-0134 JAPAN
 - Fujirebio Inc. Obihiro Facility
8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun,
Hokkaido, 080-0341 JAPAN
 - Fujirebio Inc. Distribution Center
1-17-19, Haljima-cho, Akishima-shi, Tokyo, 196-0002 JAPAN
 - Fujirebio Inc. Osaka Branch
3-9-14, Nilitaka, Yodogawa-ku, Osaka-shi, Osaka,
532-0033 JAPAN
 - Fujirebio Inc. Chubu Branch
1-21-19, Melekiminami, Nakamura-ku, Nagoya-shi, Aichi,
450-0003 JAPAN
 - Fujirebio Inc. Tohoku Branch
2-8-10, Ichiban-cho, Aoba-ku, Sendai-shi, Miyagi,
980-0811 JAPAN
 - Fujirebio Inc. Kita Kanto Branch
2-81, Miya-cho, Omiya-ku, Saltama-shi, Saltama,
330-0802 JAPAN
 - Fujirebio Inc. Chushikoku Branch
1-10-19, Hikari-machi, Higashi-ku, Hiroshima-shi, Hiroshima,
732-0052 JAPAN
 - Fujirebio Inc. Hokkaido Branch
4-1-2, Nishi, Kita-7-jo, Kita-ku, Sapporo-shi, Hokkaido,
060-0807 JAPAN
 - Fujirebio Inc. Kyushu Branch
2-10-1, Hakataeki-Higashi, Hakata-ku, Fukuoka-shi, Fukuoka,
812-0013 JAPAN

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT

