

Certificate JP06/040213

The management system of

MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.

INA LABORATORY 1063-103 Terasawaoka, Ina-shi, Nagano-ken, 396-0002 Japan



has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 October 2021 until 11 October 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 12. Certified since 11 October 2006

This is a multi-site certification. Additional site details are listed on subsequent pages.

Authorised by

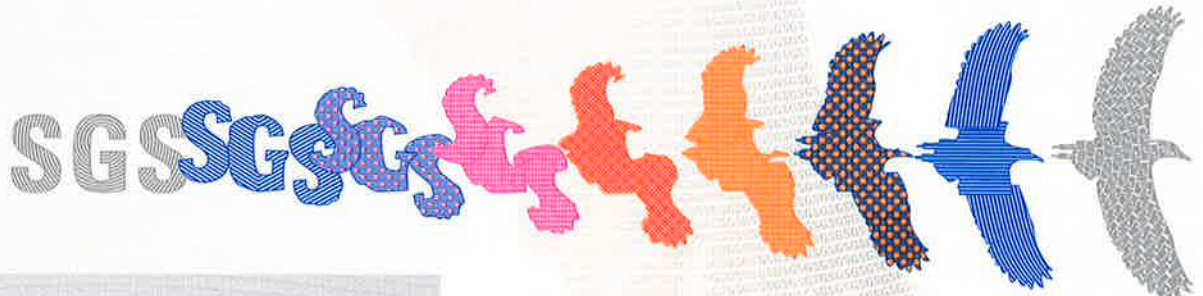


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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.

ISO 13485:2016 EN ISO 13485:2016



Issue 12

Detailed scope

1. Design and manufacture of immunological and gene technological in vitro diagnostic test kit and reagent for testing autoimmune status, cancer, coagulation and infectious diseases
2. Distribution of immunological in vitro diagnostic test kits and reagents for testing autoimmune status, cancer, infectious diseases, instruments for immunological or pathological testing and cell tissue collection devices

Additional facilities

| | |
|-----------------------------|---|
| Manufacturing Facility No.2 | 1018-1 Terasawaoka, Ina-shi, Nagano-ken, 396-0002 Japan |
| Head Office | 2-11-8 Shiba Daimon, Minato-ku, Tokyo, 105-0012 Japan |
| Nagoya Office | 4-5-3 Sakae, Naka-ku, Nagoya-shi, Aichi-ken, 460-0008 Japan |
| Tsukuba Laboratory | 25 Miyukigaoka, Tsukuba-shi, Ibaraki-ken, 305-0841 Japan |
| Distribution Center | 2-2 Kaguro Minami, Inzai-shi, Chiba-ken, 270-1369 Japan |



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