

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Immuno-Biological Laboratories Co., Ltd. 株式会社 免疫生物研究所  
1091-1 Naka 〒375-0005  
Fujioka-shi, 群馬県  
Gunma 藤岡市  
375-0005 中1091-1  
Japan

Holds Certificate No: MD 616241

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and development, and manufacture of In Vitro Diagnostic Regents for Immunoassay,  
manufacture of Materials of In Vitro Diagnostic Regents for Immunoassay.  
体外診断用医薬品（免疫学的測定法）の設計開発及び製造、体外診断用医薬品（免疫学的測定法）の原料の製造



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-10-01

Effective Date: 2021-10-01

Latest Revision Date: 2021-08-23

Expiry Date: 2024-09-30



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Location

Immuno-Biological Laboratories Co., Ltd.  
1091-1 Naka,  
Fujioka-shi,  
Gunma  
375-0005  
Japan  
株式会社 免疫生物研究所  
〒375-0005  
群馬県  
藤岡市  
中1091-1

Registered Activities

Design and development, and manufacture of In Vitro Diagnostic Regents for Immunoassay, manufacture of Materials of In Vitro Diagnostic Regents for Immunoassay.  
体外診断用医薬品（免疫学的測定法）の設計開発及び製造、体外診断用医薬品（免疫学的測定法）の原料の製造



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory) or telephone 045-414-3022

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