

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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 & EN ISO 13485:2016 for the following scope:

Design and development of In Vitro Diagnostic Regents for Immunoassay, manufacture of In Vitro Diagnostic Regents for Immunoassay and real time PCR, 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、体外診断用医薬品（免疫学的測定法、リアルタイムPCR法）の製造、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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-10-01

Effective Date: 2018-10-01

Latest Revision Date: 2018-08-29

Expiry Date: 2021-09-30

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