

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

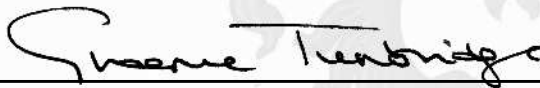
This is to certify that: **INSTITUTE OF IMMUNOLOGY Co., LTD** 株式会社特殊免疫研究所
170 Shimoishibashi, 〒329-0512
Shimotsuke-shi, 栃木県
Tochigi 下野市
329-0512 下石橋170番地
Japan

Holds Certificate No: MD 634008

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 reagents (for immunological tests).
体外診断用医薬品（免疫学的検査用試薬）の設計開発及び製造

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2015-08-11

Effective Date: 2024-08-11

Latest Revision Date: 2024-07-29

Expiry Date: 2027-08-10



Page: 1 of 2

...making excellence a habit.™

Certificate No: MD 634008

Location

INSTITUTE OF IMMUNOLOGY Co., LTD
Tochigi Plant
170 Shimoishibashi,
Shimotsuke-shi,
Tochigi
329-0512
Japan
株式会社特殊免疫研究所
栃木工場
〒329-0512
栃木県
下野市
下石橋170番地

Registered Activities

Design and development and manufacture of in vitro
diagnostic reagents
(for immunological tests).
体外診断用医薬品（免疫学的検査用試薬）の設計開発及び製造



Original Registration Date: 2015-08-11

Latest Revision Date: 2024-07-29

Effective Date: 2024-08-11

Expiry Date: 2027-08-10

Page: 2 of 2

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 or telephone 045-414-3022

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.