

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: INSTITUTE OF IMMUNOLOGY Co., LTD 株式会社特殊免疫研究所  
1-1-10 Koraku, 〒112-0004  
Bunkyo-ku, 東京都  
Tokyo 文京区  
112-0004 後楽一丁目1番10号  
Japan

Holds Certificate No: MD 634008

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, manufacture and sales 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、製造及び販売



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-08-11

Effective Date: 2018-08-11

Latest Revision Date: 2018-07-31

Expiry Date: 2021-08-10



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Certificate No: MD 634008

Location	Registered Activities
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	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
INSTITUTE OF IMMUNOLOGY Co., LTD 1-1-10 Koraku, Bunkyo-ku, Tokyo 112-0004 Japan 株式会社特殊免疫研究所 〒112-0004 東京都 文京区 後楽一丁目1番10号	Control of manufacture and sales 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）の製造管理、販売

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