



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that: **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

Holds Certificate No: MD 634008

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

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）の製造

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 2015/08/11

Latest Revision Date: 2015/08/11

Effective Date: 2015/08/11

Expiry Date: 2018/08/10

Page: 1 of 2



...making excellence a habit.™

Certificate No: MD 634008

Location	Registered Activities
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 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
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	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）の製造

Original Registration Date: 2015/08/11

Latest Revision Date: 2015/08/11

Effective Date: 2015/08/11

Expiry Date: 2018/08/10