



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM

INSTITUTE OF IMMUNOLOGY Co., LTD
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株式会社特殊免疫研究所
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Operates a QUALITY MANAGEMENT SYSTEM which complies with the requirements of ISO 13485:2016 for the activities detailed in the scope of registration.

上記組織が認証登録番号MD 634008を保有し、また下記認証登録範囲について ISO 13485:2016 の要求事項に適合した品質マネジメントシステムを実施していることをここに証します。

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

Is included as a location on Certificate number: **MD 634008**

And BSI location is: 0047555902-001

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-08-11

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