



By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM

INSTITUTE OF IMMUNOLOGY Co., LTD  
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Operates a QUALITY MANAGEMENT SYSTEM which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the activities detailed in the scope of registration.

上記組織が認証番号MD 634008を保有し、また下記認証登録範囲について ISO 13485:2016 & EN 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, 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

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

And BSI location is: 0047555902-000

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

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