

bsi.

COPY



By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM

Shino-Test Corporation  
Head Office  
3-7-9, Kanda-Surugadai, Chiyoda-ku, Tokyo 101-8410 Japan  
株式会社シノテスト  
本社  
〒101-8410東京都千代田区神田駿河台 3-7-9

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 82151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, development, manufacturing and distribution of in vitro diagnostic reagents (general, hematology, biochemistry and immunology), research reagents, calibrators and control materials.  
Manufacturing and distribution of IVD medical devices.

汎用検査、血液学的検査、生化学的検査、免疫学的検査用の体外診断用医薬品及び、研究用試薬、標準物質及びコントロール物質の設計、開発、製造及び販売  
体外診断用医療機器の製造及び販売

Is included as a location on Certificate number: **MD 82151**

And BSI location is: 0047165868-000

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: **2004-02-17**

Latest Revision Date: **2018-04-05**

Effective Date: **2016-02-17**

Expiry Date: **2019-02-16**



...making excellence a habit.™

This is not a legal document and cannot be used as such.  
To check its validity contact BSI Japan K.K. at telephone: +81 (0)3 6890 1171

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.