

Certificate of Registration

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

This is to certify that:

SENTINEL CH. S.p.A.
Via Robert Koch, 2
Milano (MI)
20152
Italy

Holds Certificate Number:

MD 504781

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of in vitro diagnostic test kits, reagents, calibrators and controls for clinical chemistry, immunochemistry, coagulation, molecular biology, rapid tests for immunology and serology; and systems and instruments for clinical diagnostics and related servicing activities.

Progettazione, sviluppo, produzione e distribuzione di kit diagnostici in vitro, reagenti, calibratori e controlli per chimica clinica, immunochimica, coagulazione, biologia molecolare, test rapidi sia per l'immunologia sia per la sierologia; e sistemi e strumenti di diagnostica clinica e attività di assistenza correlate.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2006-06-19

Latest Revision Date: 2024-06-06

Effective Date: 2024-06-19

Expiry Date: 2027-06-18



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