

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:

The design, development, manufacture and sale of in-vitro diagnostic test kits and reagent for the determination of the clinical chemistry, immunochemistry, coagulation, molecular biology, rapid tests for immunology and serology; systems and instruments for clinical diagnostic and related servicing activities.

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

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-06-19

Effective Date: 2018-06-19

Latest Revision Date: 2018-06-18

Expiry Date: 2021-06-18



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