

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SENTINEL CH. S.p.A.
Via Robert Koch, 2
Milano
Milan
20152
Italy

Facility ID Number: F000388

Holds Certificate No:

MDSAP 691187

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture and distribution of in vitro diagnostic test kits, and 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-10-23

Effective Date: 2024-06-19

Expiry Date: 2027-06-18



BSI Group America Inc. is an MDSAP recognised auditing organization

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