Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

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

DUNS Number: 42-957-2365

Holds certificate No: **MDSAP 691187**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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; system and instruments for clinical diagnostic and related servicing activities.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-10-23 Effective Date: 2018-10-23 Expiry date: 2021-06-18

MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™