

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

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

Holds Certificate No:

FM 504798

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution 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.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 08/31/2006

Effective Date: 10/02/2015

Expiry Date: 06/11/2018



CMDCAS
Recognized
Registrar



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