

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
87746-2010-AQ-ITA-SINCERT

Initial certification date:
20 December 2010

Valid:
21 December 2022 – 20 December 2025

This is to certify that the management system of
SCLAVO DIAGNOSTICS INTERNATIONAL S.p.A
Via Po, 26/28, Fraz. Pian dei Mori - 53018 Sovicille (SI) - Italy

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

Design, manufacture (also on behalf of third parties) and placing on the market of in vitro diagnostic medical devices for clinical chemistry, haematology and coagulation, serology, bacteriology and immunology analysis. System analytical validation. Design, production and placing on the market of In-Vitro diagnostic instruments for applications in Clinical Chemistry. Sales of automated systems for in vitro diagnostics

Place and date:
Vimercate (MB), 02 June 2024



SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F

EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento
SGQ, SGA, PRD, PRS, ISP, GIG, LAB e LAT, di MLA IAF
per gli schemi di accreditamento SGQ, SGA, SSI, FSM
e PRD e di MRA ILAC per gli schemi di accreditamento
LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy



Claudia Baroncini
Management Representative