

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
78107-2010-AQ-ITA-SINCERT

Initial certification date:
14 May 2010

Valid:
15 May 2022 – 14 May 2025

This is to certify that the management system of

DIAPATH S.p.A.

Via Savoldini, 71 - 24057 Martinengo (BG) - 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, installation, service, placing on the market and trade of in vitro diagnostic medical devices, including instruments, reagents and consumables for use in the field of pathologic anatomy and cytology

Place and date:
Vimercate (MB), 12 April 2022



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