



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
249031-2017-AQ-HRV-ACCREDIA

Initial certification date:
01 November 2017

Valid:
04 February 2023 – 03 February 2026

This is to certify that the management system of

BioGnost Ltd

Medjugorska 59, 10040 Zagreb, Croatia

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Development, production and place on the market of reagents and accessories for histopathology, immunohematology and microbiology. Procedure packaging and place on the market of immunochromatographic rapid tests

Place and date:
Vimercate (MB), 05 March 2025



SGQ N° 003 A	EMAS N° 009 P
SGA N° 003 D	PRD N° 003 B
SGE N° 007 M	PRS N° 094 C
SCR N° 004 F	SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GIIG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MIRA 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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Business Assurance Italy S.r.l., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 039 68 99 905. www.dnv.it