

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 d.o.o.

Međugorska 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), 03 February 2023



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

Membro di MIA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MIA 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) -

Maudio Borrun

Claudia Baroncini Management Representative

