

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
72014-2010-AQ-HRV-HAA

Initial certification date:  
21 January 2004

Valid:  
20 December 2021 – 19 December 2024

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 9001:2015**

This certificate is valid for the following scope:

**Development, production and wholesale of in vitro diagnostic reagents and medical products; and wholesale of drugs**

Place and date:  
Zagreb, 02 November 2021

For the issuing office:  
DNV - Business Assurance  
Radnička cesta 177, 10000 Zagreb, Croatia



**Franjo Potak**  
Management Representative



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
208239-2016-AE-HRV-HAA

Initial certification date:  
13 October 2016

Valid:  
27 October 2022 – 12 October 2025  
Expiry date of last certification cycle:  
12 October 2022  
Date of last re-certification:  
26 October 2022

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 Environmental Management System standard:

**ISO 14001:2015**

This certificate is valid for the following scope:

**Design, manufacture and wholesale of in vitro diagnostic reagents and medical devices**

Place and date:  
Zagreb, 27 October 2022



For the issuing office:  
DNV - Business Assurance  
Radnička cesta 177, 10000 Zagreb, Croatia

**Franjo Potak**  
Management Representative

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No:  
249031-2017-AQ-HRV-ACCREDIA

Initial certification date:  
01 November 2017

Valid:  
04 February 2020 - 03 February 2023

This is to certify that the management system of

## **BIOGNOST Ltd.**

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), 28 February  
2020**



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, GHG, 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 GL - Business Assurance  
Via Energy Park, 14, - 20871 Vimercate  
(MB) - Italy**

**Zeno Beltrami**  
Management Representative

## Declaration of Conformity Certificate Izjava o sukladnosti

Certificate No. / broj izjave 0182016-BIOG

**BIOGNOST d.o.o.**  
**Međugorska 59**  
**10040 Zagreb, Croatia**

**ensures and declares with sole responsibility, that following**

### ***In Vitro* Diagnostic Medical Devices:**

jamčimo i izjavljujemo s potpunom odgovornošću, da naši  
*In Vitro* dijagnostički medicinski proizvodi:

**Laboratory diagnostics and microscopy supplies and reagents**  
**Pribor i sredstva za laboratorijsku dijagnostiku i mikroskopiju**

See attached Product List  
Popis proizvoda u prilogu

**meet the provisions of Council Directive 98/79/EC (IVDD) which apply to us.**  
**This declaration is based on approval according to Annex III**  
**(excluding III.6) of the Directive.**

udovoljavaju svim propisanim zahtjevima Europskog Vijeća - 98/79/EC (IVDD). Ova Izjava temelji se na odobrenju prema Aneksu III (isključujući III.6) direktive.

Signed this day 16 May 2016  
Potpisano dana 16. svibnja 2016.

**BIOGNOST**  
BIOGNOST d.o.o., www.biognost.hr  
Međugorska 59, 10040 Zagreb, Croatia

.....  
Ivan Marchiotti, MD MSc  
Director  
BIOGNOST LTD.



**POPIS PROIZVODA:  
LIST OF PRODUCTS:**

**Laboratory diagnostics and microscopy supplies and reagents  
Pribor i sredstva za laboratorijsku dijagnostiku i mikroskopiju**

Product name
BioFix
BioFix C
BioFix HD
BioForm S
Bouin's solution
CitoFix
CitoSpray
CitoSpray solution
DeHematin
NB Formaldehyde concentrate 5x
4% NB Formaldehyde
4% NB Formaldehyde in transport containers
10% NB Formaldehyde
10% NB Formaldehyde in transport containers
Formaldehyde 37% for histology
OsteoFast 1
OsteoFast 2
OsteoSens
Histanol 50
Histanol 70
Histanol 80
Histanol 95
Histanol 96
Histanol 100
Histanol EP 96
Histanol EP 100
Histanol G
Histanol IP
Histanol M
BioClear
BioClear New
BioMount
BioMount High
BioMount M
BioMount New
BioMount New Low
BioMount DPX
BioMount DPX High
BioMount DPX Low
BioMount DPX Low Eco
BioMount C
BioMount T
Canada balsam
BioMount Aqua
Immersion oil
Immersion oil, type A
Immersion oil, type C
Cedarwood oil
Immersion oil, tropical grade
Immersion oil, type 37
Immersion oil, type FF
Immersion oil, type NVH
Tissue marking dyes, SET
Tissue marking dyes, green
Tissue marking dyes, yellow
Tissue marking dyes, black
Tissue marking dyes, red
Tissue marking dyes, blue



Tissue marking dyes, orange
Tissue marking dyes, lilac
Duoline i Write-On marker pens
Liquid Blocker marker pen
BioWax 52/54
BioWax 56/58
BioWax Blue
BioWax Micro
BioWax Plus 56/58
CryoFix gel
CryoFix gel, pink
CryoFix gel, blue
CryoFix gel, green
CryoFix gel, yellow
CryoSpray
DeMold spray
DeMold solution
Bluing reagent
Acid alcohol
Scott's solution
HCl Pap reagent
Hematoxylin G1
Hematoxylin G2
Hematoxylin G3
Hematoxylin H
Hematoxylin HP, Pap 1A
Hematoxylin HP, Pap 1B
Hematoxylin M
Hematoxylin ML
Hematoxylin P.T.A.
Hematoxylin W kit
Hematoxylin CAR
Hematoxylin COL
Hematoxylin Instant kit
Eosin Contrast
Eosin Contrast Plus
Eosin Y 0.5% alcoholic
Eosin Y 1% alcoholic
Eosin Y 2% alcoholic
Eosin Y 0.2% aqueous
Eosin Y 0.5% aqueous
Eosin Y 1% aqueous
Eosin Y 2% aqueous
Eosin Instant aqueous
Eosin Instant alcoholic
OG-6 reagent, Pap 2A
Orange II reagent, Pap 2B
EA 31 reagent, Pap 3A
EA 50 reagent, Pap 3B
EA 65 reagent, Pap 3C
EA 65 reagent, Pap 3D
Bio-Diff kit
Bio-Diff RTU kit
Bio-Diff 1 reagent
Bio-Diff 1 RTU reagent
Bio-Diff 2 reagent
Bio-Diff 2 RTU reagent
Bio-Diff 3 reagent
Bio-Diff 3 RTU reagent
Brilliant Cresyl Blue, solution
Hayem's solution
Leishman's solution
Tuerk's solution
May-Gruenwald solution
Giemsa solution
Wright's solution
BioGram 4 kit
Carbol Fuchsin Gram 10x concentrate
Gram Crystal Violet 1% solution
Gram Decolorizer solution 1
Gram Decolorizer solution 2



Gram Decolorizer solution 3
Gram Lugol solution
Gram Lugol solution, stabilized
Gram Safranin solution
Lugol's solution (Schiller's test)
Lugol C solution
Safranin O 5x concentrate
TB-Stain Hot kit
TB-Stain Fluorescence kit
TB-Stain Cold kit
Gabbett's reagent
Methylene Blue 10x concentrate
Methylene Blue Loeffler reagent
TB Carbol Fuchsin reagent
TB Decolorizer
TB Malachite Green reagent
TB Auramine-Rhodamine reagent
TB Decolorizer Fluorescent
TB Permanganate reagent
Lactophenol Blue solution
Lactophenol solution
A.F.O.G. kit
Alcian Blue-P.A.S. kit
Alcian Blue pH 2.5 kit
Azan trichrome kit
Congo Red Highman kit
Eosin and nigrosine vital kit
Eosin-nigrosine vital
Feulgen kit
Fouchet-Van Gieson kit
Giemsa HP kit
Gomori trichrome kit
Grimelius kit
Grocott kit
H.B.F.P. kit
Hematoxylin P.T.A. kit
Hematoxylin W kit
HemoGnost Perls kit
Luxol Fast Blue kit
Mallory trichrome kit
Masson Fontana kit
Masson trichrome kit
Masson-Goldner trichrome kit
M.I.F. kit
Movat kit
Mucicarmine kit
Oil Red O kit
Orcein kit
Paraldehyde Fuchsin kit
P.A.S. kit
P.A.S.M. kit
Rhodanine kit
Reticulin kit
Reticulin contrast kit
Sperm-Diff RTU kit
Sudan Black B kit
Sudan Black B lipid kit
UriGnost S kit
Urignost SM kit
Van Gieson trichrome kit
Von Kossa kit
Warthin Starry kit
Weigert-Van Gieson kit, rapid method
Weigert-Van Gieson kit, standard method
Acridine Orange solution
A.F.O.G. reagent
Alcian Blue solution 1%
Alcian Blue solution pH 2.5
Ammonium iron (III) sulphate, solution
Ammonia solution
Aniline, alcoholic solution



Aniline Blue reagent
Azan reagent
Azocarmine, solution
Biebrich Scarlet-Acid Fuchsin reagent
BioSchiff reagent
Benedict reagent
Chromotrope 2R/Aniline Blue reagent
Chromotrope 2R/Fast Green F.C.F. reagent
Congo Red reagent
Cresyl Violet, solution
Ehrlich aldehyde reagent
Eosin Y, isotonic solution
Eosin-nigrosine reagent
Nigrosine, izotonic solution
Fast Green F.C.F. reagent
Fast Green F.C.F. contrast reagent
Ferri reagent, Weigert B
Formaldehyde 4%, alcoholic solution
Phosphomolybdic acid, 1% solution
Phosphotungstic acid, 1% solution
Fuchsin Acid reagent
Fuchsin Acid Van Gieson reagent
Fuchsin Basic reagent
Glutaraldehyde, 4% buffered solution
Hematoxylin, Weigert A
Hydroquinone, solution
Potassium hexacyanoferrate, solution
Potassium hydroxide, solution
Potassium permanganate, 0.5% solution
Acid solution
Light Green S.F. reagent
Lithium carbonate, solution
Luxol Fast Blue, solution
Mayer's carmalum
Mayer's Mucicarmine
Methanyl yellow, solution
Methyl Blue Eosin, solution
Methenamine borate
Sodium acetate
Sodium metabisulfite, solution
Sodium tetraborate, solution
Sodium thiosulphate, solution
Sodium thiosulphate, 2% solution
Sodium thiosulphate, 5% solution
Neutral Red reagent
Nuclear Fast Red (Kernechtrot) reagent
Oil Red O reagent
Oxalic acid, 1% solution
Orange G/Aniline Blue reagent
Pandy reagent
Paraldehyde Fuchsin reagent
Periodic acid, 0.5% solution
Periodic acid, 0.8% solution
Periodic acid, 1% solution
Propylene glycol
Propylene glycol, 85%
P.T.A.-P.M.A. reagent
Dulbecco's phosphate buffered saline, pH 7.4
Dulbecco's phosphate buffered saline, pH 7.4 (conc. 10x)
Dulbecco's phosphate buffered saline, with added calcium and magnesium
Dulbecco's phosphate buffered saline, with added calcium and magnesium (conc. 10x)
Phosphate buffered saline (0.01 mol/L, pH 7.2, Tween 20)
Buffer tablets pH 6.8
Buffer tablets pH 7.2
Reagent for diferentiation in Gomori trichrome kit
Acetic acid, 1% solution
HCl reagent 0,025%
HCl reagent, A.F.O.G.
HCl reagent, Feulgen
HCl reagent, HemoGnost Perls
HCl reagent, P.A.S.





HCl reagent, Weigert-Van Gieson
Rhodanine reagent
Silver ammonia solution
Silver ammonia solution, Masson Fontana
Silver nitrate, solution for Grocott kit
Silver nitrate, solution for P.A.S.M. kit
Silver nitrate, WS solution
Silver nitrate, 5% solution
Silver nitrate, 10% solution
Sudan Black B, solution
Sudan Black B reagent
Sulphuric acid, 0,5% solution
Sulphuric acid, 3% solution
Iodine tincture, 1%
Toluidine Blue, solution
UriGnost S reagent
UriGnost SM reagent
Gold chloride, 0,2% solution
Gold chloride, 1% solution
Gold chloride, 2% solution
Gelatin, gel in transport jar



Signed this day 16 May 2016  
Potpisano dana 16. svibnja 2016.

**BIOGNOST**  
BIOGNOST d.o.o., [www.biognost.hr](http://www.biognost.hr)  
Međugorska 59, 10040 Zagreb, Croatia

A handwritten signature in purple ink, appearing to read 'Ivan Marchiotti', written over a dotted line.

Ivan Marchiotti, MD MSc  
Director  
BIOGNOST LTD.