

## DISTRIBUTION AUTHORIZATION LETTER

23 January 2021

**ECOCHIMIE SRL**  
**Cuza Voda Str, 5/1, of 403**  
**MD-2060 Chisinau**  
**MOLDOVA REPUBLIC**

**To all parties concerned about purchasing BioGnost products**

**We, BioGnost Ltd, hereby authorize ECOCHIMIE SRL as our exclusive sales agent in the territory of Republica Moldova.**

We approve their participation in tenders with our products in Hospitals, Institutes and Private Sector that will take place within the year 2021 and therefore we certify that we will supply ECOCHIMIE SRL the products which will be included in the contracts that may occur from these tenders, for as long as the contracts be valid. No other company in Moldova is authorized to sell our products on the Moldova territory.

This authorization is valid until January 2022.

Sincerely,



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

Ivan Marchiotti, MD MSc  
Director  
BioGnost Ltd  
Date: 23 January 2021

# 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  
Expiry date of last certification cycle:  
12 October 2019  
Date of last recertification:  
02 October 2019

Valid:  
25 October 2019 - 12 October 2022

This is to certify that the management system of

**BIOGNOST Ltd.**

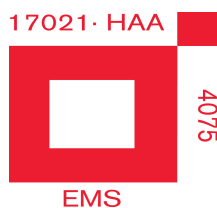
Međugorska 59, 10040 Zagreb, Croatia

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, 25 October 2019



For the issuing office:  
**DNV GL – Business Assurance**  
Buzinski prilaz 32, 10010 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 differentiation 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

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Ivan Marchiotti, MD MSc  
Director  
BIOGNOST LTD.