

### **DISTRIBUTION AUTHORIZATION LETTER**

28 August 2023

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 2023 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 September 2024.

Sincerely,





Ivan Marchiotti, MD MSc Director BioGnost Ltd Date: 28 August 2023



## 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







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

Franjo Potak Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV Adriatica d.o.o., Radnička cesta 177, 10000 Zagreb, Croatia - TEL: +385 1 2499 850. www.dnv.hr/assurance



# 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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV Adriatica d.o.o., Radnička cesta 177, 10000 Zagreb, Croatia - TEL: +385 1 2499 850. www.dnv.hr/assurance



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### **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.



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

	1
Product name	
BioFix	
BioFix C	
BioFix HD	
BioForm S	
Bouin's solution	1
CitoFix	
CitoSpray	
CitoSpray solution	1
DeHematin	
NB Formaldehyde concentrate 5x	1
4% NB Formaldehyde	
4% NB Formaldehyde in transport containers	1
10% NB Formaldehyde	1
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	4
BioMount New Low	
BioMount DPX	-
BioMount DPX High	
BioMount DPX Low	
BioMount DPX Low Eco	
BioMount C	100
BioMount T	
Canada balsam	Soft -
BioMount Aqua	
Immersion oil	
Immersion oil, type A	3
Immersion oil, type C	0240
Cedarwood oil	
Immersion oil, tropical grade	$\mathbf{X}$
Immersion oil, type 37	1/
Immersion oil, type FF	
Immersion oil, type NVH	1
Tissue marking dyes, SET	1
Tissue marking dyes, green	1
Tissue marking dyes, yellow	1
Tissue marking dyes, black	1
Tissue marking dyes, red	
Tissue marking dyes, blue	
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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	
HCI 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	LISPL REDE-
Bio-Diff 3 reagent	NOLDOVA, M
Bio-Diff 3 RTU reagent	State and a second second second
Brilliant Cresyl Blue, solution	
Leishman's solution	94.9
Tuerk's solution	Ongle T
May-Gruenwald solution	S.R.L.
Giemsa solution	100260005
Wright's solution	CU RASPUND
BioGram 4 kit	
Carbol Fuchsin Gram 10x concentrate Gram Crystal Violet 1% solution	
Gram Decolorizer solution 1	

	1
Gram Decolorizer solution 3	
Gram Lugol solution	
Gram Lugol solution, stabilized	
Gram Safranin solution	4
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	4
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	
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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	0
Oil Red O reagent	OCALA
Oxalic acid, 1% solution	MUSER
	and a stand of the
Orange G/Aniline Blue reagent	
Pandy reagent	XXEN
Paraldehyde Fuchsin reagent	221 8=11
Periodic acid, 0.5% solution	
	· 3 8
Periodic acid, 0.8% solution	- 68EB
Periodic acid, 1% solution	22 5 S (S)
Propylene glycol	Contraction States
	INDERCIE
Propylene glycol, 85%	2.5.21
P.T.AP.M.A. reagent	
Dulbecco's phosphate buffered saline, pH 7.4	
Dulbecco's phosphate buffered saline, pH 7.4 Dulbecco's phosphate buffered saline, pH 7.4 (conc. 10x)	
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, pH 7.4 Dulbecco's phosphate buffered saline, pH 7.4 (conc. 10x)	
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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	
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	
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         HCI reagent 0,025%	
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	
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         HCI reagent, 0.025%         HCI reagent, A.F.O.G.	
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         HCI reagent, 0.025%         HCI reagent, A.F.O.G.         HCI reagent, Feulgen	
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         HCI reagent, 0.025%         HCI reagent, A.F.O.G.	

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	WILLER L. FEORE
Gold chloride, 1% solution	MOLDOVA, AU
Gold chloride, 2% solution	1. July and the second s
Gelatin, gel in transport jar	1230
	ELES COULS

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



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Ivan Marchiotti, MD MSc Director BIOGNOST LTD.