



#### DISTRIBUTION AUTHORIZATION LETTER

15 January 2018

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 2018 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 December 2020.

Sincerely,

Međugorska 59, 10040 Zagreb, Croatia

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No: 72014-2010-AQ-HRV-HAA Initial certification date: 21, January, 2004

08, August, 2018 - 19, December, 2021

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, 08, August, 2018





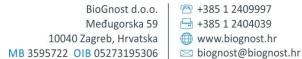
For the issuing office:

**DNV GL - Business Assurance** 

Buzinski prilaz 32, 10010, Zagreb, Croatia

Franjo Potak

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 d.o.o., www.biognost.hr Međugorska 59, 10040 Zagreb, Croatia 5 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 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
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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	
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 1111	
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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
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 TRACE
Aniline, alcoholic solution

parameters	
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.AP.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	
HCI reagent 0,025%	
HCI reagent, A.F.O.G.	
HCl reagent, Feulgen	
HCI reagent, HemoGnost Perls	
HCI reagent, P.A.S. CHIZITI	

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
lodine 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** 

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Ivan Marchiotti, MD MSc

ACHIZITII

Director

BIOGNOST LTD.

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