

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,



MANAGEMENT SYSTEM CERTIFICATE

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

Valid: 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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV GL Adriatica d.o.o., Buzinski prilaz 32, 10010 Zagreb, Croatia. TEL:+385 1 2499 850. www.dnvgl.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

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
4% ND Formaldehyde
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 Agua
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		
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 51 reagent, Pap 3A		
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		

Crem Decelerizer activitien 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		
<u>,</u>		
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 UDACTE		
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		
Mayer's Muclearnine Methanyl yellow, solution		
Methallyl yellow, solution Methyl Blue Eosin, solution		
Methy blue Losin, 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, 0.5% 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.		
HCI reagent, Feulgen		
HCI reagent, HemoGnost Peris		
HCI reagent, P.A.S. CHIZITI		

HCI 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.

