

## 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,

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



Ivan Marchiotti, MD MSc  
Director  
BioGnost Ltd  
Date: 15 January 2018

# 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

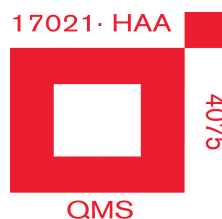
has been found to conform to the Quality Management System standard:

**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

## Declaration of Conformity Certificate

### Izjava o sukladnosti

Certificate No. / broj izjave 0462015-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:

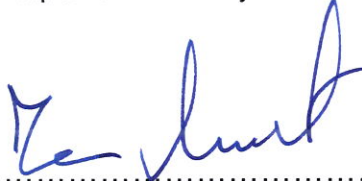
### **BIOGNOST Blood typing reagents, List A** **BIOGNOST Reagenzi za određivanje krvnih grupa, Lista A**

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  
(including III.6) of the Directive

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

Signed this day 17 Spetember 2015  
Potpisano dana 17. rujna 2015.



Ivan Marchiotti, MD MSc  
Direktor  
BIOGNOST d.o.o.

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



## Declaration of Conformity Certificate Izjava o sukladnosti

Certificate No. / broj izjave 0462015-BIOG

### BIOGNOST Blood typing reagents, List A, Product list BIOGNOST Reagenzi za određivanje krvnih grupa, Lista A, Popis proizvoda

| LISTA A |                                       |                       |
|---------|---------------------------------------|-----------------------|
| 1.      | Anti-A MonoGnost reagens              | za pločicu i epruvetu |
| 2.      | Anti-B MonoGnost reagens              | za pločicu i epruvetu |
| 3.      | Anti-AB MonoGnost reagens             | za pločicu i epruvetu |
| 4.      | Anti-A1 lektin reagens                | za epruvetu           |
| 5.      | Anti-H MonoGnost reagens              | za pločicu i epruvetu |
| 6.      | Anti-D MonoGnost MG reagens           | za pločicu i epruvetu |
| 7.      | MonoGnost kontrolni reagens           | za pločicu i epruvetu |
| 8.      | Anti-D MonoGnost M reagens            | za pločicu i epruvetu |
| 9.      | Anti-CDE MonoGnost reagens            | za pločicu i epruvetu |
| 10.     | Anti-C MonoGnost reagens              | za pločicu i epruvetu |
| 11.     | Anti-E MonoGnost reagens              | za pločicu i epruvetu |
| 12.     | Anti-c MonoGnost reagens              | za pločicu i epruvetu |
| 13.     | Anti-e MonoGnost reagens              | za pločicu i epruvetu |
| 14.     | Anti-C <sup>w</sup> MonoGnost reagens | za pločicu i epruvetu |
| 15.     | Anti-K MonoGnost reagens              | za epruvetu           |
| 16.     | Anti-D MonoGnost komplet              | za epruvetu           |

Signed this day 17 September 2015  
Potpisano dana 17. rujna 2015.



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Direktor  
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## Declaration of Conformity Certificate Izjava o sukladnosti

Certificate No. / broj izjave 0532015-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:

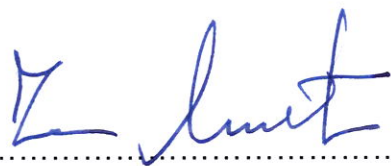
### **BIOGNOST Blood typing reagents, List B** **BIOGNOST Reagenzi za određivanje krvnih grupa, Lista B**

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**  
**(including III.6) of the Directive**

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

Signed this day 27 October 2015  
Potpisano dana 27. listopada 2015.



Ivan Marchiotti, MD MSc  
Direktor  
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# Declaration of Conformity Certificate

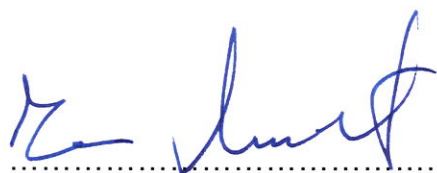
## Izjava o sukladnosti

Certificate No. / broj izjave 0532015-BIOG

### BIOGNOST Blood typing reagents, List B, Product list BIOGNOST Reagenzi za određivanje krvnih grupa, Lista B, Popis proizvoda

| LISTA B |  |                                   |
|---------|--|-----------------------------------|
| 1.      | Anti-humani serum                      | dir./ indir. antiglobulinski test |
| 2.      | Anti-humani globulin MonoGnost reagens | dir./ indir. antiglobulinski test |
| 3.      | Anti-IgG serum                         | dir./ indir. antiglobulinski test |
| 4.      | Anti-IgG MonoGnost reagens             | dir./ indir. antiglobulinski test |
| 5.      | Anti-C3d MonoGnost reagens             | direktni antiglobulinski test     |
| 6.      | Bio-LISS reagens                       | indirektni antiglobulinski test   |
| 7.      | Albumin 22% reagens                    | indirektni antiglobulinski test   |
| 8.      | Bromelin reagens                       | za pločicu i epruvetu             |
| 9.      | Bio-ZZAP reagens                       | za pločicu i epruvetu             |
| 10.     | Pozitivni kontrolni serum              | za epruvetu                       |
| 11.     | Anti-k MonoGnost reagens               | za epruvetu                       |
| 12.     | Anti-S MonoGnost reagens               | za epruvetu                       |
| 13.     | Anti-s MonoGnost reagens               | za epruvetu                       |
| 14.     | IgG kontrolni eritrociti               | za epruvetu                       |
| 15.     | A1 eritrociti                          | za epruvetu                       |
| 16.     | A2 eritrociti                          | za epruvetu                       |
| 17.     | B eritrociti                           | za epruvetu                       |
| 18.     | O eritrociti                           | za epruvetu                       |
| 19.     | Anti-Le <sup>a</sup> MonoGnost reagens | za epruvetu                       |
| 20.     | Anti-Le <sup>b</sup> MonoGnost reagens | za epruvetu                       |

Signed this day 27 October 2015  
Potpisano dana 27. listopada 2015.



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Direktor  
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