DNV·GL

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

17021· HAA
4075
QMS

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

Digitally signed by Turcu Nicolae
Date: 2019.04.04 15:33:18 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
Ksaverska c. 4, 10000 ZAGREB, CROATIA
Tel.: ++ 385 1 4884 100, Fax: + +385 1 4884 110
e-mail: halmed@halmed.hr
www.halmed.hr
OIB 37926884937

Klasa: 530-04/16-01/35
Ur. br.: 381-13-07/36-16-02
Zagreb, 10.08.2016.

Biognost d.o.o.,
Republika Hrvatska, Zagreb,
Međugorska 59

POTVRDA O SLOBODNOJ PRODAJI
(CERTIFICATE OF FREE SALE)

Agencija za lijekove i medicinske proizvode Republike Hrvatske ovim putem potvrđuje da niže navedeni medicinski proizvod ispunjava zahtjeve Zakona o medicinskim proizvodima („Narodne novine“, br. 76/13.) te Pravilnika o bitnim zahtjevima, razvrstavanju, upisu proizvođača u očevidnik proizvođača, upisu medicinskih proizvoda u očevidnik medicinskih proizvoda te ocjenjivanju sukladnosti medicinskih proizvoda (Narodne novine, br. 84/13.), kojima se prenose direktive o medicinskim proizvodima Europske unije.

The Agency for Medicinal Products and Medical Devices of the Republic of Croatia herby certifies, that medical device listed below, is in the conformity with the Medical Devices Act („Official Gazette“, No. 76/13.) Ordinance on Essential Requirements, Classification, Entry into the Register of Manufacturers and Medical Devices and Assessment of Conformity of Medical Devices ("Official Gazette", No. 84/13) transposing the medical devices directives of the European Union.

Medicinski proizvod:
Medical Device:

Reagensi za histopatologiju
Klasa rizika in vitro dijagnostika - ostalo / Risk Class – in vitro diagnostics Others

Proizvođač:
Manufacturer:

Biognost d.o.o.,
Republika Hrvatska,
Zagreb,
Međugorska 59

nalazi se u prometu u Republici Hrvatskoj, te se slobodno izvozi.
is marketed in Republic of Croatia, and is free to export.

Ravnatelj Agencije / *Head of Agency*

Izv. prof. dr. sc. Siniša Tomić

Upravna pristojba u iznosu od 40,00 kuna po Tar. br. 1 i Tar. br. 4 Tarife upravnih pristojbi Zakona o upravnim pristojbama („Narodne novine“, broj 8/96., 77/96., 95/97., 131/97., 68/98., 66/99., 145/99., 116/00., 163/03., 17/04., 110/04., 141/04., 150/05., 153/05., 129/06., 117/07., 25/08., 60/08., 20/10., 69/10., 126/11., 112/12., 19/13., 80/13., 40/14., 69/14., 87/14., 94/14.) je plaćena.

Dostaviti:
1. Naslovu
2. Pismohrana – ovdje.

BIOGNOST ®
FARMACEUTSKI I DIJAGNOSTIČKI PROIZVODI

BioGnost d.o.o.
Međugorska 59
10040 Zagreb, Hrvatska
MB 3595722 OIB 05273195306

+385 1 2409997
+385 1 2404039
www.biognost.hr
biognost@biognost.hr

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

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Ivan Marchiotti, MD MSc
Director
BIOGNOST LTD.