

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

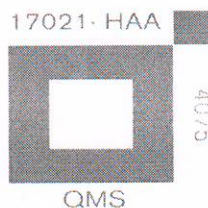
has been found to conform to the Quality Management System standard:
ISO 9001:2015

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

CERTIFICATE OF ANALYSIS

Product name: METHYLENE BLUE LOEFFLER SOLUTION

Lot: MBL-22/17

Expiry date: 29.08.20.

Product description

- Product code: MBL-OT-100, MBL-OT-250, MBL-OT-500, MBL-OT-1L, MBL-OT-2.5L
- Product name: METHYLENE BLUE LOEFFLER SOLUTION

Intended use

- Bacteriology

Chemical and physical data

- Aggregate state: liquid
- Appearance: blue liquid
- Relative density (20 °C): 0.97 g/cm³
- Boiling point: 100 °C
- Flash point: 40 °C
- Solubility (20 °C): soluble
- pH value: 8,126 (acceptable range: 8.0-8.6)

Warning and hazard signs

Classification according to (EC) 1272/2008 (CLP)

- Danger
- GHS02
- H226
- P210
- P233
- P280

Storage

- Store at +15°C to +25°C

QA result

- PASSES TEST

We declare that the product bearing the above mentioned lot number is manufactured in accordance with the technical specifications, tested in a diagnostic laboratory and it complies with all standard requirements.

BioGnost Ltd.

BIOGNOST
BIOGNOST d.o.o. www.biognost.hr
Medjugorski put 10040 Zagreb, Croatia



Vladimir Ramljak, professor of biology
Quality assurance and quality control manager

Zagreb, 31 August 2017



CERTIFICATE OF ANALYSIS

Product name: **BIOGRAM 4 KIT**

Lot: BGR4-65/17

Expiry date: 14.06.20.

Product description

- Product code: BGR4-100T, BGR4-K-100, BGR4-K-250, BGR4-K-500
- Product name: BIOGRAM 4 KIT

Intended use

- Microscopy, microbiology

Results of control staining

- Gram-positive bacteria - blue-purple
- Gram-negative bacteria - red

Storage

- Store at +15°C to +25°C

QA result

- PASSES TEST

We declare that the product bearing the above mentioned lot number is manufactured in accordance with the technical specifications, tested in a diagnostic laboratory and it complies with all standard requirements.

BioGnost Ltd.

BIOGNOST
BIOGNOST d.o.o., www.biognost.hr
Medugorje 11 k.o. Zagreb, Croatia



Vladimir Ramljak, professor of biology
Quality assurance and quality control manager

Zagreb, 29 August 2017

