

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 46 din 03.07.2023

Solicitantul „Neotec” SRL, cu sediul mun.Chisinau, str.Zaikin, 37, tel./fax: 022 852250/ 022 852252, e-mail office@neotec.md, agb@neotec.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. Analizator biochimic, automat 300 teste, cu sistem de tip deschis BA-A-380

Se anexează următoarele acte:

1. Actul prin care producătorul își desemnează reprezentantul.
2. Declarație pe proprie răspundere
3. EC Declaration Of Conformity
4. EC Certificat

Data 03.07.2023

Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:39:35 EEST
Reason: MoldSign Signature
Location: Moldova

Semnătura _____



Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: „Neotec” SRL, cu sediul în mun.Chisinau, str.Zaikin, 37,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. Analizator biochimic, automat 300 teste, cu sistem de tip deschis BA-A-380

Sunt autentice și corespund realității.

Botnaru Andrei- Director

Numele, prenumele și funcția

Semnătura _____

Data 03.07.2023



We, BIOEVOPEAK CO., LTD.,

based in BLDG. 3, LIGAOGUOJIHUAYUAN, NO. 1222, WEST AOTI ROAD, LIXIA DISTRICT, JINAN, SHANDONG P.C.: 250100, assign **Neotec SRL**, based in Str I. Zaikin 37, Chisinau MD -2005, Moldova, as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Sales representative

Date: March 30, 2023

Signed: 2023.3.30



Digitally signed by Botnaru Andrei
Date: 2023.06.22 13:57:20 EEST
Reason: MoldSign Signature
Location: Moldova





Bioevopeak Co., Ltd.

NO.4 BLDG MINGSHI HAOTING, JINGSHI ROAD, LIXIA DISTRICT,
JINAN CITY, SHANDONG PROVINCE, CHINA. P.C.: 250100
TEL: +86-531-88982330 FAX: +86-531-88983691
EMAIL: info@bioevopeak.com WEBSITE: www.bioevopeak.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully
2014/35/EU Low Voltage Directive and 2014/30/EU Electromagnetic Compatibility Directive have been taken
as reference for these processes

Company Name: Bioevopeak Co., Ltd.

Brand: BIOEVOPEAK

Related Directives and Annex: 2014/35/EU Low Voltage Directive (LVD)
2014/30/EU Electromagnetic Compatibility (EMC)

Related Standards: EN 61326-1:2013; EN 61010-1:2010

Product(s): Fully Automatic chemistry Analyzer

Type(s)/Model(s): BA-A-120; BA-A-160; BA-A-200; BA-A-280; BA-A-380; BA-A-480;

Parameters: AC110-240 V, 50Hz/60Hz

Classification: Medical diagnostic equipment

Examination Period: March 29, 2021

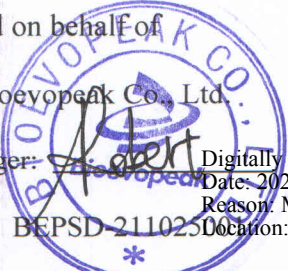
Date of Expiry: March 29, 2026

Review Result: We, Bioevopeak Co., Ltd. declare that during the self-testing and
performance evaluation, no Non-compliance according to the requirements
of the Low Voltage Directive 2014/35/EC and Electromagnetic
Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: 2021

Signed for and on behalf of

Company: Bioevopeak Co., Ltd.

General Manager:  Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:38:07 EEST

Document No: BEPSD-2110250000 Reason: MoldSign Signature
Location: Moldova



Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:38:18 EEST
Reason: MoldSign Signature
Location: Moldova



CERTIFICATE

ATTESTATION CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been observed and audit has been completed successfully.

2014/30/EU Electromagnetic Compatibility Directive and
2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name : Bioevopeak Co., Ltd.

Company Address : 1-1509, No.4 Bldg Mingshi Haoting, Jingshi Rd, Jinan City,
Shandong Province, China

Related Directives and Annex : 2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility Directive

Related Standards : EN 61010-1:2010/A1:2019, EN 61326-1:2013

Product Name : Chemistry Analyzer

Report No and Date : EC.BIO.20211202007-R-3

Product Brand/Model/Type : BA-A Series, BA-A-A Series, BA-A-B Series, BA-A-C Series,
BA-A-D Series, BA-A-E Series, BA-A-F Series, BA-A-G Series,
BA-PA Series, BA-PA-A Series, BA-PA-B Series, BA-PA-C Series,
BA-PA-D Series, BA-PA-E Series, BA-PA-F Series, BA-PA-G Series,
BA-SA Series, BA-SA-A Series, BA-SA-B Series, BA-SA-C Series,
BA-SA-D Series, BA-SA-E Series, BA-SA-F Series, BA-SA-G Series,
BA-VA Series, BA-VA-A Series, BA-VA-B Series, BA-VA-C Series,
BA-VA-D Series, BA-VA-E Series, BA-VA-F Series, BA-VA-G Series

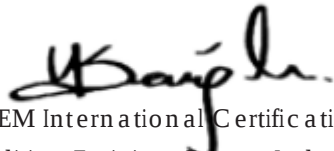
Certificate Number : M.2021.206.C69445

Initial Assessment Date : 03.12.2021

Registration Date : 06.12.2021

Reissue Date/No : -

Expiry Date : 05.12.2026


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

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