

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 51 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 hematologic, automat (3 diff), tip deschis, 60 probe HEMA-D6190

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: 2023.06.23 10:35:05 EEST
Reason: MoldSign Signature
Semnătura Moldova



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 hematologic, automat (3 diff), tip deschis, 60 probe HEMA-D6190

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: 2023.06.23 10:26:33 EEST
Reason: MoldSign Signature
Location: Moldova





Bioevopeak Co., Ltd.

RM.2014,BLDG.3,LIGAOGUOJIHUAYUAN,NO.1222,WEST AOTI
ROAD,LIXIA DISTRICT,JINAN,SHANDONG. 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 Regulation (EU) 2017/746 on in vitro diagnostic medical devices have been taken as reference for these processes

Company Name: Bioevopeak Co., Ltd.

Brand: BIOEVOPEAK

Related Directives and Annex: Regulation (EU) 2017/746 on in vitro diagnostic medical devices

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

Product(s): Auto Hematology Analyzer

Type(s)/Model(s): HEMA-D6031;HEMA-D6190;HEMA-D6130;HEMA-D6051;
HEMA-D6052;HEMA-B6051Mini;

Parameters: 220V,50 Hz

Classification: Laboratory Equipment

Examination Period: July 28, 2022

Date of Expiry: July 27, 2027

Review Result: We, Bioevopeak Co., Ltd.declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices was detected.

Year of DOC marking: 2022

Signed for and on behalf of

Company: Bioevopeak Co., Ltd.

General Manager: 

Document No: BEPSD-220728001



Digitally signed by Botnaru Andrei
Date: 2023.06.23 10:31:11 EEST
Reason: MoldSign Signature
Location: Moldova





International Inspection & Certification Body

Digitally signed by Botnaru Andrei
Date: 2023.06.23 10:30:51 EEST
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Location: Moldova



ATTESTATION OF COMPLIANCE CERTIFICATE

According to 2014/35/EU Low Voltage Directive, 2014/30/EU Electromagnetic Compatibility Directive

Certificate Number	: FMK.21/AC.C0193.01
Certification Body	: Femko International Technical Control Training Certification Ltd. Co. Kazım Dirik Mah. 372/7 Sok. No:8 Bornova Izmir Turkey
Certificate Holder and Address	: Bioevopeak Co., Ltd. 1-1509, No.4 Bldg Mingshi Haoting, Jingshi Rd, Jinan City, Shandong Province, China
Manufacturer of The Test Sample	: Bioevopeak Co., Ltd. 1-1509, No.4 Bldg Mingshi Haoting, Jingshi Rd, Jinan City, Shandong Province, China
Product Commercial Brand	: Bioevopeak
Product Description & Specifications	: Hematology Analyzer
Type & Model Scope	: HEMA-B6031, HEMA-B6051, HEMA-B6091, HEMA-B6130, HEMA-B6150, HEMA-B6190, HEMA-B6031Mini, HEMA-B6051Mini, HEMA-B6091Mini, HEMA-B6130Mini, HEMA-B6150Mini, HEMA-B6190Mini, HEMA-D6031, HEMA-D6051, HEMA-D6091, HEMA-D6130, HEMA-D6150, HEMA-D6190, HEMA-D6031Mini, HEMA-D6051Mini, HEMA-D6091Mini, HEMA-D6130Mini, HEMA-D6150Mini, HEMA-D6190Mini
Directive & Regulations	: 2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compatibility Directive
Harmonised Standards	: EN 61010-1:2010+A1:2019, EN 61326-1:2013
Submitted Documents	: Declaration of Conformity
Number & Date of Test Report	: EC.BIO.20211119004-R-4 22.11.2021

Result: Based on the Declaration of Conformity, The company has declared that the assembled product compliance with the 2014/35/EU Low Voltage Directive and 2014/30/EU Electromagnetic Compatibility Directive published by the European Parliament and Council and the relevant standards. Safety components, essentially parts, drawings, assembly and installation procedures are the responsibility of the company and, the CE marking below can only be used at the manufacturer's responsibility after the completion of the EC Declaration of Conformity for all relevant Directives. This certificate covers only the product(s) mentioned above. In case of any change in the product(s), FEMKO must be notified. This certificate, which must be returned upon request, remains the property of FEMKO. The aforementioned company above must keep a copy of this document for 10 years from the date of registration of the document.

Date of Decision	: 25.11.2021
Place of Issue	: Izmir-Turkey
Date of Expiry	: 25.11.2026
Revision No	:
Revision Date	:

AYÇA DEMİROK
Conformity Assessment
Coordinator



Femko Inspection & Certification
Femko Ulus. Tek. Kont. Eğt. Belg. Ltd. Şti.
www.femko.com.tr

