Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

Notificare
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 50 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 şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. **Analizator hematologic, automat (3 diff), tip deschis 40 probe HEMA-D6031**

Se anexează următoarele acte:
1. Actul prin care producătorul își desemnează reprezentantul.
2. Declaratie pe proprie raspundere
3. EC Declaration Of Conformity
4. EC Certificat

Data 03.07.2023 Semnătura

Digitally signed by Botnaru Andrei
Date: 2023.06.23 10:32:30 EEST
Reason: MoldSign Signature
Location: 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	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: „Neotec" SRL, cu sediul in mun.Chisinau, str.Zaikin, 37,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Analizator hematologic, automat (3 diff), tip deschis 40 probe HEMA-D6031**

Sunt autentice și corespund realității.

Botnaru Andrei- Director
Numele, prenumele şi funcţia

Semnătura

Digitally signed by Botnaru Andrei
Date: 2023.06.23 10:33:10 EEST
Reason: MoldSign Signature
Location: Moldova

Data 03.07.2023

Bioevopeak

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.

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

Year of DOC marking: **2022**

Signed for and on behalf of

Company: Bioevopeak Co., Ltd.

General Manager

Document No: BEPSD-220728001

CE

FEMKO
International Inspection & Certification Body

Digitally signed by Botnaru Andrei
Date: 2023.06.23 10:30:51 EEST
Reason: MoldSign Signature
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 Europen 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 retumed 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

CE

CERTIFIED FEMKO CERTIFIED

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