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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

Notificare
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 44 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 semiautomat, de urina cu masurare continue UA-SA-300**

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

Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:33:44 EEST
Reason: MoldSign Signature
Location: Moldova

Data 03.07.2023 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	

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 semiautomat, de urina cu masurare continue UA-SA-300**

Sunt autentice și corespund realității.

Botnaru Andrei- Director
Numele, prenumele şi funcţia *Semnătura* _____

Data 03.07.2023

Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:34:42 EEST
Reason: MoldSign Signature
Location: Moldova

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

Aurora Ma

BIOEVOPEAK CO., LTD.

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

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Date: 2023.06.22 14:15:47 EEST
Reason: MoldSign Signature
Location: Moldova

EU Declaration of Conformity

Manufacturer:	Bioevopeak Co., Ltd. Add: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong, China.
European Representative:	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain
SRN:	ES-AR-000001202
Product Name:	Urine Analyzer
GMDN Code:	35918
Basic UDI-DI:	697548844UA22S3

Intended Use: This urine analyzer is match with urine strips to use for medical establishment to conduct semi-quantitative or qualitative detection of biochemical components in human urine samples.

Classification (IVDR, Annex VIII): Class A, Rule 5.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Applied standards, common specification, guidance:
ISO 14971:2019, IEC 61010-1:2010+A1:2016, IEC 61010-2-101:2018, IEC 61326-1:2020, IEC 61326-2-6:2020, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 62366:2015+AC:2015, EN 62304:2006+A1:2015, EN ISO 15223-1:2021.

Signature:

Name:
Position: General Manager

Place/date: China, Nov.11th, 2022

CE

File No.: XC/22-05, ver.A/0

Digitally signed by Botnaru Andrei
Date: 2023.06.22 14:15:38 EEST
Reason: MoldSign Signature
Location: Moldova

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Regulation (EU)2017/746 Riomavix S.L.performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Bioevopeak Co., Ltd.

ADDRESS: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Regulation (EU)2017/746 including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the General Safety and Performance Requirements of the European Council Regulation (EU)2017/746.

IVD Devices: Urine Analyzer

Classification: Class A

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU)2017/746 are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is **RPS/5356/2022**

RIOMAVIX

Issue date: 30/Nov/2022
Cert. No.: R20220601-5

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