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. 1 din 12.11.2023

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 biochimic, semiautomat, cu sistem de tip deschis BA-SA-100D

Se anexează următoarele acte:
1. Lista dispozitivelor medicale solicitate spre notificare
2. Actul prin care producătorul își desemnează reprezentantul.
3. Declaratie pe proprie raspundere
4. EC Declaration Of Conformity
5. EC Certificate

Data 12.11.2023 Semnătura

Digitally signed by Botnaru Andrei
Date: 2023.10.26 13:44:18 EEST
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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 deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARATIE 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 biochimic, semiautomat, cu sistem de tip deschis BA-SA-100D

Sunt autentice și corespund realității.

Botnaru Andrei -Director

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Date: 2023.10.26 13:46:28 EEST
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Location: Moldova

Numele, prenumele şi funcţia *Semnătura* _____

Data 12.11.2023

EU Declaration of Conformity

Manufacturer:	Infitek 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:	Biochemistry Analyzer
GMDN Code:	56667
Basic UDI-DI:	697548844BA22MW

Intended Use: The instrument is auto chemistry analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal fluid 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 62366:2015+AC:2015, EN 62304:2006+A1:2015, EN ISO 15223-1:2021.

Signature:

Name:
Position: General Manager

Place/date: China, Jul.15th, 2023

INFITEK CO., LTD.

Digitally signed by Botnaru Andrei
Date: 2023.10.26 13:44:26 EEST
Reason: MoldSign Signature
Location: Moldova

File No.: CE/23-01, ver.A/0

Infitek

Make the laboratory smarter, safer
more accurate, and more convenient.

Manufacturer's Authorization

To whom it may concern

We, ***Infitek Co.,Ltd,*** based in 17th Floor, Mingsheng Building, High-tech Zone, Jinan City, Shandong State, China 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, 90/385/EEC and and the regulation 2017/746.

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: 17th Floor, Mingsheng Building, High-tech Zone, Jinan City, Shandong State, China

Date: September 8, 2023

Signed:

INFITEK CO.,LTD Infitek

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Date: 2023.10.26 13:44:43 EEST
Reason: MoldSign Signature
Location: Moldova

INFITEK.CO.,LTD
TEL: +86-531-88982330 FAX: +86-531-88983691
Website: infitek.com Email: info@infitek.com
Address: 17th Floor, Mingsheng Building, High-tech Zone, Jinan City

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: Infitek Co., Ltd.

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

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: Biochemistry 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/4788/2022**

RIOMAVIX

RIOMAVIX

RIOMAVIX

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Location: Moldova

Issue date: 08/Aug/2023
Cert. No.: R20230807-1

CE