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. 81 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. **Sterilizator 200 L DOF-HAS200A**

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

Digitally signed by Botnaru Andrei
Date: 2023.06.23 11:49:29 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. **Sterilizator 200 L DOF-HAS200A**

Sunt autentice și corespund realității.

Botnaru Andrei- Director

Numele, prenumele şi funcţia *Semnătura* _____

Digitally signed by Botnaru Andrei
Date: 2023.06.23 11:49:59 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 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):	Sterilizing Oven
Type(s)/Model(s):	DOF-HAS25 II;DOF-HAS55 II;DOF-HAS80 II;DOF-HAS140 II; DOF-HAS250 II;DOF-HAS30E;DOF-HAS45E;DOF-HAS65E; DOF-HAS85E;DOF-HAS125E;DOF-HAS230E;DOF-HAS20A; DOF-HAS50A;DOF-HAS70A;DOF-HAS100A;DOF-HAS200A; DOF-HAS45B;DOF-HAS72B;DOF-HAS125B;DOF-HAS210B
Parameters:	220V,50 Hz
Classification:	Laboratory Equipment
Examination Period:	February 7, 2023
Date of Expiry:	February 6, 2028
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: **2023**
Signed for and on behalf of

Company: Bioevopeak Co., Ltd.

General Manager:

Digitally signed by Botnaru Andrei
Date: 2023.06.23 11:38:47 EEST
Reason: MoldSign Signature
Location: Moldova

Document No: BEPSD-230207001

BEP-Version: LVD & EMC DOC 1.0

Digitally signed by Botnaru Andrei
Date: 2023.06.23 11:38:41 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 61010-2-040:2015, EN 61326-1:2013
Product Name	: Autoclave & Sterilizer
Report No and Date	: EC.BIO.20220117006-R-1
Product Brand/Model/Type	: BCS Series, BGS Series, STGB Series, STP-A Series, STP-E Series, STP-M Series, STC Series, STB-N Series, STB-BZ Series, STB-BB Series, STB-B-2A Series, STB-B-2B Series, STB-B-3A Series, STB-B-3C Series, STB-NA Series, STB-B-3D Series, STB-B-3B Series, STB-N Series, STH Series, STH-ND Series, STV Series, STV-AI Series, STV-AII Series, STV-I Series, STV-II Series, STV-III Series, STV-APV Series, DOF-HAS II Series, DOF-HAS E Series, DOF-HAS Series, STV-PV Series, STB Series, STP Series
Certificate Number	: M.2021.206.C70868
Initial Assessment Date	: 18.01.2022
Registration Date	: 19.01.2022
Reissue Date/No	: -
Expiry Date	: 18.01.2027

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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