

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 6 din 03.07.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.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:

Biobase Bioindustry

Product: Incubator

Model:

1. BJPX-H30II

2. BJPX-H48II

Se anexează următoarele acte:

1. Declarație de conformitate
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

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	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

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:

Biobase Bioindustry

Product: Incubator

Model:

- 1. BJPX-H30II**
- 2. BJPX-H48II**

Sunt autentice și corespund realității

Alexandru Grabazei, director

Semnătura _____

Data: **03.07.2023**

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

No. 51 South Gongye Road, Jinan, Shandong, China 250100

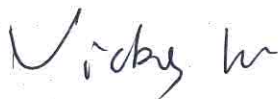
Fax: +86-531-81219804 Website: www.biobase.cc

Date: 18th. October. 2017.

Authorization

We, the undersigned Biobase Biodustry(Shandong) Co., Ltd., No. 51 South Gongye Road, Jinan, Shandong, China 250100, hereby appoint F.C.P.C. "DataControl" S.R.L., 20, Melestiu street, MD-2001, Chişinău, Republic of Moldova, to be official representative for registration, renewal, variation of registration, etc. at the responsible authorities of the Republic of Moldova.

Signature:



On behalf of Manufacturer: Biobase Biodustry(Shandong) Co., Ltd.

Title: Sales Supervisor

Seal:



BIOBASE

Biobase Bioyu Co., Ltd.
ADD: No. 7888 Jingshi Road, Jinan, Shandong, China
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU have been taken as reference for these processes

Company Name: Biobase Bioyu Co., Ltd.

No. 7888 Jingshi Road, Jinan, Shandong, China.

Related Directives and Annex: **2014/35/EU Low Voltage Directive (LVD)**
2014/30/EU Electromagnetic compatibility (EMC)

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

Product(s): Constant-Temperature Incubator

Type(s)/Model(s): BJPX-H30II, BJPX-H48II, BJPX-H80IV, BKN-110F

Classification: Laboratory Equipment

Examination Period: September 12, 2022

Date of Expiry: September 11, 2027

Review Result: We, Biobase Bioyu 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/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: 2022

For and on behalf of

Biobase Bioyu Co., Ltd.

RA Specialist: Chloe Cheng

Document No: BKSD-6022091209



BIOBASE

BIOBASE BIODUSTRY (SHANDONG) CO., LTD.

ADD: Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China
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E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU have been taken as reference for these processes

Company Name: **Biobase Biodustry (Shandong) Co., Ltd**
Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

SRN: CN-MF-000025015

Related Directives and Annex: **2014/35/EU Low Voltage Directive (LVD)**
2014/30/EU Electromagnetic compatibility (EMC)

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

Product(s): Constant-Temperature Incubator

Type(s)/Model(s): BJPX-H50IV, BJPX-H80IV, BJPX-H160IV, BJPX-H270IV, BJPX-H30II, BJPX-H48II
BJPX-H64II, BJPX-H123II, BJPX-H230II

Classification: Laboratory Equipment

Examination Period: June 16, 2022

Date of Expiry: June 15, 2027

Review Result: We, Biobase Biodustry (Shandong) 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/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

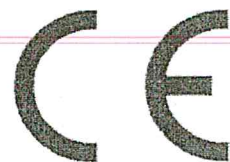
Year of DOC marking: 2022

Signed for and on behalf of

Company: **Biobase Biodustry (Shandong) Co., Ltd**

RA Specialist: *Chloe Cheng*

Document No: BKSD-CC22061603



Version: BKSD2022 LVD & EMC DOC 1.0

Touch Screen Constant-Temperature Incubator

Features:

- * Large LCD touch screen.
- * D type: with inner glass door.
G type: with viewing window.
- * Microprocessor controller.
- * Stainless steel chamber.

Safety Functions:

- * Over temperature alarm.
- * Independent limit temperature alarm system.
- * Leakage current and over-voltage protector.

Standard Accessories:



Test port

Optional Accessories:



Base stand



Footmaster Caster



UV lamp

Technical Parameters:

Model	BJPX-H54BK(D/G)	BJPX-H88BK(D/G)	BJPX-H160BK(D/G)
Capacity	54L	88L	160L
Temperature Control Method	PT100		
Temperature Range	RT+5~85°C		
Temperature Stability	±0.5°C (at 37°C)		
Temperature Uniformity	±1°C (at 37°C)		
Ambient Temperature	5~30°C, recommend 25°C±2°C		
Timing Range	0~99.9h		
Shelves	2pcs/adjustable		
Power Consumption	345W		495W
Power Supply	AC220V±10%, 50/60Hz(Standard); AC110±10%, 60Hz(Optional)		
Internal Size(W*D*H)mm	395*346*395	500*364*500	558*518*600
External Size(W*D*H)mm	D type: 536*588*681 G type: 522*626*587	D type: 650*573*793 G type: 627*621*692	D type: 718*732*890 G type: 685*779*790
Package Size(W*D*H)mm	D type: 606*648*818 G type: 592*676*724	D type: 720*630*930 G type: 697*671*829	D type: 788*792*1027 G type: 755*829*927
Gross Weight(kg)	D type: 51 G type: 44	D type: 65 G type: 51	D type: 89 G type: 69

Constant-Temperature Incubator

Features:

- * Large LED display, multiple groups of data to be displayed at a time; function of timing and over-temperature protection.
- * Two-layer toughened-glass observation window.



BJPX-H30/48/64/123II



BJPX-H230II

Technical Parameters:

Model	BJPX-H30II	BJPX-H48II	BJPX-H64II	BJPX-H123II	BJPX-H230II
Capacity	30L	45L	65L	125L	230L
Temp. Range	RT+5~80°C				
Temp. Fluctuation	±0.2°C				
Time Setting	1~9999mins				
Shelves	2 pcs/adjustable				
Consumption	150W	250W	500W	600W	700W
Power Supply	AC220V±10%, 50/60Hz(Standard); AC110±10%, 60Hz(Optional)				
Internal Size(mm)	310*310*310	350*350*350	400*360*450	500*450*550	600*500*750
External Size(mm)	460*510*695	500*550*735	550*550*840	636*680*915	730*670*1220
Package Size(mm)	550*570*765	620*585*800	640*640*905	730*720*1000	900*800*1350
Gross Weight(kg)	51	56	62	71	105