

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 4 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: Refrigerator

Model:

- 1. BPR-5V118**
- 2. BPR-5V238**
- 3. BPR-5V298**
- 4. BPR-5V628**

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: Refrigerator

Model:

- 1. BPR-5V118**
- 2. BPR-5V238**
- 3. BPR-5V298**
- 4. BPR-5V628**

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

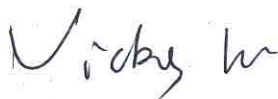
Fax: +86-531-81219804 Website: www.biobase.cc

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, Chişinau, 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:





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

Company Address : Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan, Shandong, China

Related Directives and Annex : **2014/35/EU Low Voltage Directive**
2014/30/EU Electromagnetic Compatibility Directive

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

Product Name : **Refrigerator**

Report No and Date : TELMJ1903223021

Product Brand/Model/Type : BPR-5V50(G), BPR-5V50(F), BPR-5V70(G), BPR-5V70(F), BPR-5V95(G), BPR-5V95(F), BPR-5V100(G), BPR-5V100(F), BPR-5V130(G), BPR-5V130(F), BPR-5V260, BPR-5V360, BPR-5V650, BPR-5V758, BPR-5V1000, BPR-5V1500, BPR-5V160, BPR-5V250, BPR-5V310, BPR-5V588, BBR-4V120, BBR-4V160, BBR-4V210, BBR-4V250, BBR-4V310, BBR-4V650, BBR-4V1000

Certificate Number : **M.2019.206.C0569**

Initial Assessment Date : 03.04.2019

Registration Date : 04.04.2019

Reissue Date/No : -

Expiry Date : **03.04.2024**

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)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

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E-mail: info@udemltd.com.tr www.udem.com.tr

UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



Laboratory Refrigerator



118L



238L



298L



628L/968L

Technical Parameters

Model		BPR-5V116	BPR-5V238	BPR-5V298	BPR-5V628	BPR-5V968
External Size(W*D*H) mm		500*550*1300	580*575*1810	620*575*1980	1220*630*1885	1220*860*1885
Capacity		118L	238L	298L	628L	968L
Temp. Range		2℃-8℃				
Temp. Accuracy		0.1℃				
Control System		Microprocessor Control, Large Screen LED Display				
Alarm		Audible and visual alarm for: High and low temperature, Power failure alarm, Door ajar,Thermostat failure				
Refrigeration Type		Forced air refrigeration system				
Refrigerant		R600a, CFC Free			R134a, CFC Free	
Condenser & Evaporator		Bundy tube condenser				
Defrost		Manual defrost Auto defrost				
Construction	Structure	Unibody Design & Mono-assembly foaming (Rigid polyurethane insulation material)			Unibody Design & Mono-assembly foaming (Polyurethane cyclopentane insulation material)	
	Internal Material	Embossed aluminum sheet			Spraying steel plate	
	External Material	Spraying steel plate				
Shelves		4 pcs	4pcs	5 pcs	10 pcs	
Door		Glass door with electric heating				
Consumption		162W	162W	189W	537W	
Power Supply		AC220V±10%, 50/60Hz(only for BPR-5V118) ,AC110/220V±10%, 50/60Hz				
Standard Accessories		LED Lamp,USB port, probe access port(BPR-5V628 & BPR-5V968)				
Optional Accessory		Temperature recorder, Temperature printer(USB port can not be selected at the same time), probe access port				
Package Size(W*D*H) mm		590*595*1380	670*650*1870	700*650*2030	1340*750*2100	1340*980*2100
Gross Weight		51kg	68kg	84kg	235kg	262kg

Laboratory Refrigerator(2-8°C)



Laboratory Refrigerator(2-8°C)

