

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 Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____ TRIUMF MOTIV SRL _____, cu
sediul _____ or. Chișinău str. Grenoble 193 _____,

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:

Refractometer	BK-R670
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Sunt autentice și corespund realității.

Numele, prenumele și funcția Jighili Tatiana, Administrator
Semnătura _____

Data 09.06.2023

BIOBASE

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)

TEL: +86-531-66777727 FAX: +86-531-81219804

E-MAIL: sales_middleeast@biobase.com WEBSITE: www.biobase.cc

AUTHORIZATION LETTER

Date: June 9, 2023

To whom it can refer

We, Biobase Biodustry(Shandong) Co., Ltd.

Address: Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

hereby authorizes your company:

Triumf Motiv SRL

Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

tel: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand in your country.

This letter of authorization remains valid for five years, starting from June 9, 2023 and expiring on June 9, 2028.

Name: Erica Zhang

Title: Sales Manager

Signature:



Portable Digital Refractometers



PDR-series



PDR-F series

Technical Parameters:

Model	Scale	Range	Min. reading	Accuracy	Temp. Range	Temp. Precision	Power Supply	Packing Size(W*D*H) mm	G.W. (kg)
PDR-WN1	MASS S/W(%)	0~35%	0.1	±0.2	0°C~40°C (32°F~104°F)	±0.5°C(1°F)	2 x AAA (1.5V)	165*95*60	0.35
	VOL AP(%)	0~22%	0.1	±0.1					
	Oe(Germany)	0~150	1	±1					
	KMW	0~25	0.1	±0.1					
PDR-WN2	MASS S/W(%)	0~35%	0.1	±0.2					
	VOL AP(%)	0~22%	0.1	±0.1					
	Oe(Germany)	30~150	1	±1					
	KMW	0~25	0.1	±0.1					
PDR-WN3	MASS S/W(%)	0~35%	0.1	±0.2					
	VOL AP(%)	0~22%	0.1	±0.1					
	Oe(Germany)	0~150	1	±1					
	KMW	0~25	0.1	±0.1					
PDR-K1	Soybean milk concentration	0~35%	0.1	±0.3					
PDR-C1	Glycol	32~50°F	0.1 °F	±1 °F					
	Propanediol	32~50°F	0.1 °F	±1 °F					
	Battery fluid	1.00~1.50sg	0.01 sg	±0.01 sg					
	Clearance	0~40°F	0.1 °F	±1 °F					
PDR-C2	Glycol	0~50°C	0.1°C	±1 °C					
	Propanediol	0~50°C	0.1 °C	±1 °C					
	Battery fluid	1.00~1.50sg	0.01 sg	±0.01 sg					
	Clearance	0~40°C	0.1°C	±1 °C					

Refractometer

Application:

BK-R670 Automatic Refractometer includes high-performance CCD light-sensitive part, can accurately and efficiently process sample analysis tests through unique signal acquisition, analysis and processing technology.



Features:

- * Cloud service system, connecting cloud database with instruments;
- * 7" LCD touch screen and innovative WINDOWS software interface
- * 2 USB ports, RS232 port and internet port for connecting printer or internet, U disk and SD card port for data exporting.
- * Perfect measuring prism
 - Measuring prism is made of high hardness sapphire glass, of excellent properties against corrosion and scratches, free for clean and durable.
- * Ultra long life light source
 - It adopts High brightness LED lights with service life exceeding 100000 hours
- * Auto temperature control system
 - It adopts Peltier temperature control system, make sure the whole testing with accuracy and constant temperature.

Technical Parameters:

Model	BK-R670
Refractive Index Measuring Range	1.30000~1.70000nD
Measuring Error	±0.0001nD
Measuring Resolution	0.0001/0.00001(switchable)
Brix Measuring Range	0~100%
Measuring Error (Brix)	±0.1%
Measuring Resolution (Brix)	0.1%/0.01%(switchable)
Temperature Control Mode	Peltier temperature controller
Temperature Measuring Range	0~100°C
Temperature Control Range	5~80°C
Temperature Control Accuracy	±0.02°C
Interface	RS232, USB, Ethernet interface
Data Storage Capacity	4G
Display	7" TFT LCD touch screen
Consumption	45W
Power Supply	100~240VAC (15V 7.0A)
External Size(W*D*H)	365*300*150mm
Package Size(W*D*H)	490*420*300mm
Gross Weight	8kg

BIOBASE

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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)

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): **Refractometer**

Type(s)/Model(s): **BK-R670**

Classification: **Laboratory Equipment**

Examination Period: **October 18, 2022**

Date of Expiry: **October 17, 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 DOG marking: 2022

RA Specialist: Roxanne Yan

Document No: ★ BKSD-R22101804

