

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-2 din 14.07.2023

Cappillary Centrifuge	BCK-MH12-B
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Data 14.07.2023

Semnătura

(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 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:

<u>Cappilary Centrifuge</u>	<u>BCK-MH12-B</u>
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Sunt autentice și corespund realității.

Numele, prenumele și funcția Jighili Tatiana, Administrator
Semnătura _____

Data 14.07.2023

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:



BIOBASE

JINAN BIOBASE MEDICAL CO.,LTD.

ADD:NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, 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

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

Company Name: JINAN BIOBASE MEDICAL CO.,LTD.

NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, JINAN,
SHANDONG,CHINA

Brand: BIOBASE

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): Capillary Centrifuge

Type(s)/Model(s): BKC-MH12-B

Classification: Laboratory Equipment

Examination Period: April 27, 2023

Date of Expiry: April 26, 2028

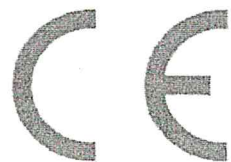
Review Result: We, JINAN BIOBASE MEDICAL CO.,LTD., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: 2023

For and on behalf of
JINAN BIOBASE MEDICAL CO., LTD.

RA Specialist: *Roxanne Yan*
Authorized Signature(s)

Document No: BKSD-R23042702





C E R T I F I C A T E

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 : JINAN BIOBASE MEDICAL CO., LTD.

Company Address : NO.019 QISHAN ROAD, LAIWU HIGH TECH ZONE, 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 : Centrifuge

Report No and Date : EC.BIOBASE.20210727001-R-1

Product Brand/Model/Type : See Annex Page

Certificate Number : M.2021.206.C66658

Initial Assessment Date : 02.08.2021

Registration Date : 03.08.2021

Reissue Date/No : -

Expiry Date : 02.08.2026


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





C E R T I F I C A T E

ANNEX of Certificate No: M.2021.206.C66658

Product Brand/Model/Type

: BKC-VL8RL-B, BKC-VL6RL-B, BKC-VL6RL-BI, BKC-VL5RL-B, BKC-VL6RCL, BKC-VL5RMCL, BKC-VH10RL-B, BKC-TL5RL-B, BKC-TL5RCL, BKC-TL5RMCL, BKC-TH21RL-B, BKC-VL6L-B, BKC-VL6L-BI, BKC-VL6L-BII, BKC-VL6KCL, BKC-VL5KL, BKC-VL5KCL, BKC-TL5RM, BKC-TL5RM-I, BKC-TL5RM-IC, BKC-TL6RM, BKC-TL4M, BKC-TL5M, BKC-TL5M-I, BKC-TL5M-II, BKC-TL6M, BKC-TL5M-IC, BKC-TL5MC, BKC-TL5M-IIC, BKC-TL4G, BKC-TL5G, BKC-TLCT4Y, BKC-TLCT5Y, BKC-TL4X, BKC-TH21RM, BKC-TH25RM, BKC-TH16RM, BKC-TH18RM, BKC-TH20RM, BKC-TH26RM, BKC-MH12-B, BKC-MH16-B, BKC-MH16-BI, BKC-MH18-B, BKC-MH20-B, BKC-TL4C, BKC-TL5E, BKC-TL6K, BKC-TL6A, BKC-TL6E, BKC-TL5EC, BKC-TL4A, BKC-TL5ER, BKC-TL7RML, BKC-TL6BL, BKC-TH10RA, BKC-TH12R-B, BKC-TH10R-B, BKC-TH21RMC, BKC-TH21R-B, BKC-TH21RM-B, BKC-TL5REC, BKC-TH28M, BKC-TH12, BKC-TH16E, BKC-TH16WC, BKC-TH18I, BKC-TH18WC, BKC-TH18IC, BKC-TH21WC, BKC-TH16RE, BKC-TH20R-B, BKC-TH16R-B, BKC-TH21RWC, BKC-TH18RMC, BKC-TH18RWC, BKC-TH18RW, BKC-TH16RMC, BKC-TCT1, BKC-TCT2, Mini-7, Mini-12, Mini-4, Mini-5, BKC-AU5MT, BKC-AU5KT, BKC-AU5BT, BKC-AUV5ML, BKC-AUV5BL, BKC-AUV5TL, BKC-AUV5KL, BKC-AUV5RL, BKC-AUV5RKL, BKC-AU5ML, BKC-AU5KL, BKC-AU5AL, BKC-TL5PI, BKC-TL5P, BKC-TL6RMCL, BKC-TL6RMBL, BKC-T7RMC, BKC-L6K, BKC-OIL4P, BKC-TL5RRL, DDL-8R, DDL-6R, DGL-10R, TDL-5R, TGL-21R, DD-6R, DD-6R-I, DD-6R-II, TDL-5M, TDL-5M-I, TD-4M, TD-5M, TD-5M-I, TD-5M-II, TD-6M, TD-4G, TD-4Y, TD-4X, TD-5G, TGL-21M, TGL-25M, TGL-16M, TGL-18M, TGL-20M, TGL-26M, TG-12W, TG-16W, TG-16W-I, TG-18W, TG-20W, TD-4C, TD-5E, TDL-5E, CDL-7M, TD-6K, TD-6A, TD-6B, TD-6E, GL-10A, GL-12K, G-12K, TGL-16E, TG-16E, Cytoprep-1, Cytoprep-2, Mini-7, Mini-12, TGL-20K, TGL-16K, TG-18I, DDL-5R, DDL-6R-I, TD-5MT, DD-5MT, DDL-5RT, TDL-5MT, TD-5Y, TD-5R, GL-28M, TD-5EC, DL-5EC, TDL-5RC, TD-5M-IC, TDL-5M-IC, TD-5MC, GL-10K, TD-4A, Mini-4, Mini-5, TD-5P-I, TD-5P, GL-21MC, GL-21M, TD-5M-IIC, DL-6MC, DL-6MB, CDL-7MC, DD-6K, DD-6KC, TD-4P, TDL-5MC, TGL-21MC, TG-21WC, TGL-18MC, GL-21K, TG-18WC, TGL-16MC, TG-16WC, TGL-18WC, TGL-18W, TG-18IC, TDL-5AT, TD-5BT, TDL-5KT, TD-5KT, DD-5KT, DD-5BT, DDL-5KT, DD-5IT, TDL-6M, , DD-5K, DD-5KC, DDL-6RC, DDL-5MC

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