La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitivelor Medicale

## **NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale nr. <u>TR-73</u> din <u>27.07.2023</u>

Solicitantul TRIUMF MOTIV S	RL, cu sediu	ul <u>or. Chişinău str. Grenoble 19</u> (adresa)	<u>3_</u>
tel /fav:	022768462	, e-mail <u>triumf.motiv@mail.r</u>	11
solicit înregistrarea în Registrul de categorii și tipuri de dispozitive medi pe piață a:	stat al dispo	ozitivelor medicale a următoare	elor
Denumire generică (denumirea dispo	zitivului)	Modelul	
High Speed Mini Centrifuge		D2012 Plus	Ц 
Se anexează următoarele acte:  DECLAȚIE DE CONFORMITATE CE CERTIFICATUL DE CONFORMITATE Scrisoare de autorizare de la produc  Data 27.07.2023  Tabelul de recepț (se completează de către Agenție solicitant)	cător ionare a noti		
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			

Data <u>27.07.2023</u>

Către Agenția Medicamentului și Dispozitive Medicale

# **DECLARATIE PE PROPRIE RĂSPUNDERE**

Solicitant: TRIUMF MOTIV SRL

	or. Cilişiriau	str. Grenoble 193				
decla	r pe proprie răspu	ındere, cunoscând preve	derile art. <b>352<sup>1</sup></b> , Codul Penal al			
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate						
pentru notificarea dispozitivului medical:						
Denumire generică (denumirea dispozitivului)		Modelul				
High Speed Mini Centrifuge		D2012 Plus				
Sun	it autentice și co	orespund realității.				



Dated on 9st June 2023

## LETTER OF AUTHORIZATION

We, **DLAB Scientific Co., Ltd.**, located in No.31, Yu'an Road, Airport Economic Core Area, Shunyi District, Beijing, China, declare herewith that assign

Triumf Motiv SRL, based in Str Grenoble 193, Chisinau MD -2011, Moldova

as authorized representative to import, to offer, to sell direct or via sub-dealer, to participate in tenders, to install and to provide after sales service for the equipment manufactured under the brand DLAB Scientific Co., Ltd. on the territory of the Republic of Moldova.

The authorization is valid till April 30<sup>th</sup>, 2024.

Sincerely,

Sales and Marketing director

Siumui Chan

# CERTIFICATE

# of Conformity

# **Electrical Equipment (Safety) Regulations 2016**

(UK SI 2016 No. 1101)

Registration Nr.: AQ 50537057 0001 Report Nr.: CN21QOTV 001

Holder: DLAB SCIENTIFIC CO.,LTD.

Yu An Road 31,

Airport Economic core zone,

Shun yi District, Beijing, 101318 P.R. China

Product: Centrifuge (High Speed Mini Centrifuge)

**Test standard:** BS EN 61010-1:2010+A1 BS EN 61010-2-020:2017

Identification:

D2012 plus, SCI-12, 90X2002121 (X=0-9, X stands for different client)

This certificate of conformity is based on an evaluation of a sample of the above mentioned product, technical report and documentation. This certificate does not imply the assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

**Certification Body** 

Date: 2022-05-23

Miao Mai

UK

The UKCA mark may be used, if all relevant UK Legislations and the UK Declaration of Conformity has been completed.



## TUV Rheinland UK Ltd.

Friars Gate (Third Floor), 1011 Stratford Road, Shirley, Solihull, B90 4BN



# Certificate



Certificate no.

CU 72225557 01

#### **License Holder:**

DLAB SCIENTIFIC CO., LTD. Yu An Road 31, Airport Economic core zone, Shun yi District, Beijing, 101318 P.R. China

#### **Manufacturing Plant:**

DLAB SCIENTIFIC CO., LTD. Yu An Road 31, Airport Economic core zone, Shun yi District, Beijing, 101318 P.R. China

Test report no.: USA-SOS CN223TRY 001

Client Reference: SHI HONGYUN

Tested to:

UL 61010-1:2012 R7.19

CAN/CSA-C22.2 NO. 61010-1-12 + GI1 + GI2 (R2017) + A1

Certified Product: High Speed Mini Centrifuge

License Fee - Units

8

Model Designation: D2012 plus, SCI-12, 90X2002121

(X=0-9, X stands for different client)

Rating:

Adaptor: AC 100-240 V, 50/60 Hz, 200 VA

EUT: DC 24 V, 100 W

Appendix: 1

**Licensed Test mark:** 



**Date of Issue** (day/mo/yr) 11/05/2022



Date : 2022/05/11

DLAB SCIENTIFIC CO.,LTD. Yu An Road 31, Shun yi District, Beijing, 101318 P.R. China

Attn: Shi Hongyun

#### Re. : CU US + Canada Certificate

Type of Equipment: High Speed Mini Centrifuge

Model Designation : See Certificate Certificate No. : CU 72225557 0001 File No. : CN223TRY 001

Engineer/Contact : Sven Olaf Steinke
Standard(s) : UL 61010-1:2012 R7.19

CAN/CSA-C22.2 NO. 61010-1-12 + GI1 + GI2 (R2017) +

Α1

Dear Madame or Sir,

The above referenced technical equipment has been tested and was found to be in compliance with the listed test requirement(s). Enclosed, please find the TUV Rheinland approval document No. CU 72225557 0001. It authorizes you to label the listed product(s) with the TUV Rheinland Mark identified in the approval document. For compliance, the Test Mark must be on the approved unit.

Your product is subject to regular factory follow-up inspections as well as annual certificate and factory registration fees.

In using the TUV Rheinland Mark you are obligated to comply with the TUV Rheinland of North America Service Agreement.

If we can be of any further assistance to you, please do not hesitate to contact us.

Sincerely yours, Certification Body

Paddy Qiu QA Certification Officer

Enclosure



JPTUV-133327

## IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

## **CB TEST CERTIFICATE**

Product

Name and address of the applicant

Name and address of the manufacturer

Name and address of the factory

Ratings and principal characteristics

Trademark (if any)

Customer's Testing Facility (CTF) Stage used Model / Type Ref.

Additional information (if necessary may also be reported on page 2)

A sample of the product was tested and found to be in conformity with

As shown in the Test Report Ref. No. which forms part of this Certificate

High Speed Mini Centrifuge

DLAB SCIENTIFIC CO., LTD.

Yu An Road 31,

Airport Economic core zone, Shun yi District, Beijing,

101318, P.R. China

DLAB SCIENTIFIC CO., LTD.

Yu An Road 31,

Airport Economic core zone, Shun yi District, Beijing,

101318, P.R. China

DLAB SCIENTIFIC CO., LTD.

Yu An Road 31,

Airport Economic core zone, Shun yi District, Beijing,

101318, P.R. China

Adaptor: AC 100-240 V, 50/60 Hz, 200 VA EUT: DC 24 V, 100 W

DLAB

D2012 plus, SCI-12, 90X2002121

(X=0-9, X stands for different client)

For model difference, refer to the test report.

TEC 61010-2-020:2016

IEC 61010-1:2010+A1

See Test Report for National Differences

CN22R75D

This CB Test Certificate is issued by the National Certification Body



2022-04-12

TÜV Rheinland Japan Ltd.

Global Technology Assessment Center

4-25-2 Kita-Yamata, Tsuzuki-ku Yokohama 224-0021, Japan

Phone + 81 45 914-3888 Fax + 81 45 914-3354 Mail: info@jpn.tuv.com

Web : www.tuv.com

Xuhua Liu

Date:

Signature:





of Conformity

Registration No.: AK 50224350 0001

Report No.: 16801118 001

Dragon Laboratory Instruments Limited F3, Block 12, Yu Hua Road 28, Area B, Konggang Industrial Development Zone, Shunyi District, Beijing 101318 P.R. China Holder:

Product: **Laboratory Equipment** 

(High Speed Mini Centrifuge)

Identification:

Type Designation: D2012 plus

Serial No.: Engineering Sample

Remark: Refer to test report 16801118 001 for details.

Clause 13 of IEC/EN 61010-2-020:2006 Bioseal not

evaluated.

Tested acc. to: EN 61010-1:2001

> EN 61010-2-020:2006 IEC 61010-1:2001 IEC 61010-2-020:2006

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of

TÜVRheinland

Tifizierun9

conformity.

**Certification Body** 

Mai Miao

20.03.2012 Date

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

# CERTIFICATE



of Conformity Low Voltage Directive 2014/35/EU

Registration No.: AN 50537052 0001

Report No.:

CN219ZKO 001

Holder:

DLAB SCIENTIFIC CO.,LTD.

Yu An Road 31,

Airport Economic core zone,

Shun yi District, Beijing, 101318

P.R. China

**Product:** 

Laboratory Equipment

(High Speed Mini Centrifuge)

Identification:

Type Designation: D2012 plus SCI-12 90X2002121

(X=0-9,X stands for different client)

(DLAB)

Serial No.: Engineering sample

Remark: Refer to test report CN219ZKO 001 for details.

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with Annex I of Council Directive 2014/35/EU, referred to as the Low Voltage Directive. This certificate does not imply assessment of the series-production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to Annex IV of the Directive.

Certification Body

Date 12.04.2022

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

## **TÜV Rheinland (China) Ltd.** Member of TÜV Rheinland Group



DLAB SCIENTIFIC CO., LTD.

Shi Hongyun

Date : 12.04.2022 Our ref. : Jiangx 01 Your ref.: S. H. Y

Yu An Road 31, Airport Economic core zone, Shun yi District, Beijing, 101318 P.R. China

Ref : AN Certificate of Conf. Low Voltage D.

Type of Equipment : High Speed Mini Centrifuge

Model Designation : See Certificate Certificate No. : AN 50537052 0001 Report No. : CN219ZKO 001

Dear Shi Hongyun,

We herewith confirm that a sample of the above mentioned technical equipment has been tested and was found to be in accordance with the relevant requirements.

Enclosed please find your Certificate of Conformity.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

With kind regards,

Certification Body

Enclosure

邮编: 100176

Fax: 86 10 8524 2200 e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

Tel: 86 10 8524 2222