

|                                                                                                       |  |
|-------------------------------------------------------------------------------------------------------|--|
| Comentarii cu privire la<br>acceptul/refuzul recepționării<br>notificării, inclusiv motivul refuzului |  |
| Data/nr. de ordine atribuit notificării<br>de către Agenție (în cazul acceptării<br>recepționării)    |  |
| Numele, prenumele, funcția<br>persoanei responsabile de<br>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. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

|            |         |
|------------|---------|
| Centrifuge | TDZ5-SX |
|------------|---------|

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția* Jighili Tatiana, Administrator  
*Semnătura* \_\_\_\_\_

*Data* 09.06.2023

## LETTER OF AUTHORIZATION

We, AELAB GUANGZHOU CO.,LTD, based in Room 2504, No.2-6 Hongde Rd, Guangzhou, Guangdong, China, assign Triumph Motiv SRL, based in Str Grenoble 193, Chisinau MD -2011, Moldova, as our exclusive distributor to promote, quote and sell our products , as well as to participate in all kinds of public and private tenders.

The company Triumph Motiv SRL , is eligible to submit a bid, and subsequently negotiate and sign the contract with you for the goods supplied by us.

Furthermore we confirm that Triumph Motiv SRL is responsible for the warranty and after sale service since they has been provided with full training on initial installation, service and maintenance.

This letter is valid 12monthes.

Place: Guangzhou, China

Date: June 8, 2023

Signed





Test Report / Technical Construction File no. 20ZCTE1124003ER, 20ZCTS1124001SP

Hunan Xiangxin Instrument and Meter  
Co., Ltd.  
Rm 602-A11 building, Tongxin industrial park, No.169  
Huizhi middle Rd, Hi-tech delvelopment zone,  
Changsha, China



The image shows the ENETEC logo, which is a circular emblem with a blue border. Inside the circle, the text "ENTE CERTIFICAZIONE MACCHINE" is written in white at the top, and "SAFETY COMPLIANCE MARK" is written in white at the bottom. In the center of the circle is a map of Europe with the words "European Conformity" overlaid in red. To the right of the logo is a dark blue rectangular badge with the words "Type Approved" in white, and a registered trademark symbol (®) in a circle above it.

Centrifuge  
(see the following annex)

Standard:  
EN 61010-1:2010+A1:2017, EN 61326-1:2013,  
EN IEC 61000-3-2:2019,  
EN 61000-3-3:2013+A1:2019

related to CE Directive(s):  
2014/35/EU (Low Voltage)  
2014/30/EU (Electromagnetic Compatibility)

Additional information and clarification about the Marking:



**Expiry date: 29 November 2025**

Approver  
ECM Service Director  
Luca Bedonni



Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY  
 ☎ +39 051 6705141 🖨 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it



# Annex I

No. 4Q201130.HXISN77

Test Report / Technical Construction File no. 20ZCTE1124003ER, 20ZCTS1124001SP

## Model(s):

DL8M-12L, DL-7MC, DL-6MC, DL-5MC, DL-4MC, DL-6M, DL-5M, DL-5MX, DL-4M, TDL-6MC, TDL-5MC, TDL-6M, TDL-5M, TDL-4MC, TDL-4M, TDL-3MC, TDL-3M, TDL-420, TDL-5MX, TDZ6-WS, TDZ5-WS, TDZ5-SX, TD5A-WS, TD6A-WS, TD5B-WS, TD6B-WS, DD6-MC, DD5-MC, TD5A, TD5B, TD4ZA, TD6, TD4ZB, TD4A-WS, TD4A, TDZ4-WS, TD4Z-WS, TD4N-WS, TD4, TDZ3-WS, DD8-MC, DD7-MC, DD6-MC, DD5-MC, DD4-MC, DD4-M, TDD6-MC, TDD5-MC, TDD-4MC, TDD-3MC, TDD-3M, TDZ4-SX, TG24-WS, TG22-WS, TG20-WS, TG18-WS, TG16-WS, TG16-W, TG18, TG12-WS, TG10-WS, TG12-W, TG10-W, TG-8W, TG-7W, GL-26MC, TG25-MC, TG-24MC, GL-22MC, GL-21MC, GL-20MC, GL-18MC, GL-16MC, GL-12MC, GL-10MC, XY-80K, TGL-24MC, TGL-22MC, TGL-20MC, TGL-18MC, TGL-16MC, RGL-10MC, TGL-24M, TGL-22M, TGL-20M, TGL-18M, TGL-16M, TGL-10M, TGL-22X, TGL-20X, TGL-18X, TGL-16X, TGD-22MC, TGD-20MC, TGD-18MC, TGD-18M, TGD-16MC, TGD-20, TGD-18, TD4-TM, DD4-TM, DL4-TM, TD4-CXC, TD4Z-XB, TD4-MR, TD4-ZF, TD4-PRP, TD4-NY, TD5-G, X-707, X-708, ZZB7, ZZB8, ZZB10, DD5-XK, TD5-JY, DTM162, DTM120, TDM108, TM80, TD5-PRP, TD5-ZF, TD6-PRP

# Certificate of Compliance

No. 4Q201130.HXISN77

Test Report / Technical Construction File no. 20ZCTE1124003ER, 20ZCTS1124001SP

Certificate's Holder: AELAB GUANGZHOU CO.,LTD

Room 2504, No.2-6 Hongde Rd, Guangzhou, Guangdong, China

Product: Centrifuge

Model(s): DL8M-12L, DL-7MC, DL-6MC, DL-5MC, DL-4MC, DL-6M, DL-5M, DL-5MX,  
DL-4M, TDL-6MC, TDL-5MC, TDL-6M, TDL-5M, TDL-4MC, TDL-4M, TDL-3MC,  
TDL-3M, TDL-420, TDL-5MX, TDZ6-WS, TDZ5-WS, TDZ5-SX, TD5A-WS, TD6A-WS,  
TD5B-WS, TD6B-WS, DD6-MC, DD5-MC, TD5A, TD5B, TD4ZA, TD6, TD4ZB,  
TD4A-WS, TD4A, TDZ4-WS, TD4Z-WS, TD4N-WS, TD4, TDZ3-WS, DD8-MC,  
DD7-MC, DD6-MC, DD5-MC, DD4-MC, DD4-M, TDD6-MC, TDD5-MC,  
TDD-4MC, TDD-3MC, TDD-3M, TDZ4-SX, TG24-WS, TG22-WS, TG20-WS,  
TG18-WS, TG16-WS, TG16-W, TG18, TG12-WS, TG10-WS, TG12-W, TG10-W,  
TG-8W, TG-7W, GL-26MC, TG25-MC, TG-24MC, GL-22MC, GL-21MC,  
GL-20MC, GL-18MC, GL-16MC, GL-12MC, GL-10MC, XY-80K, TGL-24MC,  
TGL-22MC, TGL-20MC, TGL-18MC, TGL-16MC, RGL-10MC, TGL-24M,  
TGL-22M, TGL-20M, TGL-18M, TGL-16M, TGL-10M, TGL-22X, TGL-20X,  
TGL-18X, TGL-16X, TGD-22MC, TGD-20MC, TGD-18MC, TGD-18M,  
TGD-16MC, TGD-20, TGD-18, TD4-TM, DD4-TM, DL4-TM, TD4-CXC, TD4Z-XB,  
TD4-MR, TD4-ZF, TD4-PRP, TD4-NY, TD5-G, X-707, X-708, ZZB7, ZZB8, ZZB10,  
DD5-XK, TD5-JY, DTM162, DTM120, TDM108, TM80, TD5-PRP, TD5-ZF, TD6-PRP

Verification to: Standard: EN 61010-1:2010+A1:2017, EN 61326-1:2013,  
EN IEC 61000-3-2:2019, EN 61000-3-3:2013+A1:2019

related to CE Directive(s):  
2014/35/EU (Low Voltage)  
2014/30/EU (Electromagnetic Compatibility)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use. Additional information and clarification about the Marking: The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

**Issuance date: 30 November 2020**

**Expiry date: 29 November 2025**

Reviewer

Technical expert

Elc

GUANGZHOU CO., LTD  
广州微德仪器仪表有限公司  
Guangzhou



# QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that the Quality Management System of  
**AELAB GUANGZHOU CO.,LTD**

**Registered Address:** 2504,2-6 Hongde Road,Haizhu District,Guangzhou

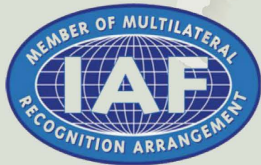
**Audit Address:** 2504,2-6 Hongde Road,Haizhu District,Guangzhou

by reason of its  
Quality Management System  
has been awarded this certificate for compliance with standard  
**GB/T 19001-2016 / ISO 9001:2015**

for the  
Sales of laboratory analytical instruments

**Certificate No:** HIC230256  
**Unified Social Credit Code:** 914401050589238870  
**Date Of Initial Certification:** 24 Feb 2023  
**Certificate Expiry:** 23 Feb 2026

签发



中国认可  
国际互认  
管理体系  
MANAGEMENT SYSTEM  
CNAS C194-M



Please scan QR code to check  
the certification validity

未经贴标  
证书无效

First supervision  
Qualified sign

未经贴标  
证书无效

Second supervision  
Qualified sign

This certificate is issued by Shenzhen Hua Kai Inspection & Certification Co., Ltd., the certified organizations shall regularly accept the supervision. This certificate shall be used in conjunction with the "Notice of Supervisory Qualification" issued by HIC. and if the certificate is marked with a qualified sign, it indicates that the certificate holder has passed the supervision and can keep the registration qualification. For obtaining the validity of the certificate, please visit [http:// www.hicgroup.com.cn](http://www.hicgroup.com.cn).  
The certificate information is also available on the CNCA official website: <http://www.cnca.gov.cn>

**HIC Certification Service**

## Benchtop Low-Speed centrifuge TDZ5-SX



TDZ5-SX is a very popular high performance table top low speed centrifuge. With microprocessor control, brush-less motor and less noise, it's widely used in Hospitals, clinic, bio-chemistry and bio-science research laboratories etc.

### Features

1. Stainless steel material, simple-compact, low-noise. and microprocessor control, maintenance-free frequency conversion motor.
2. Both electronic lock and mechanical lock for safe operation.
3. 10 grades of Acc/Dec rate, which can be set or save parameters freely.
4. Parameters can be modified at any time when running without stopping the machine, and enable to show both the set and the actual value when running.
5. It's widely used in qualitative analysis of blood serum, plasma and urea in hospital, blood center and biochemistry.

### Technical parameters

|                  |                                     |           |            |
|------------------|-------------------------------------|-----------|------------|
| Model            | TDZ5-SX                             |           |            |
| Max Speed        | 5000r/min                           |           |            |
| Speed Accuracy   | ±30rpm                              |           |            |
| Max RCF          | 3500×g                              |           |            |
| NO.1 Angle Rotor | 12×10/15ml                          | 5000r/min | RCF 3500×g |
| NO.2 Swing Rotor | 16×10/15ml                          | 4000r/min | RCF 2810×g |
| NO.3 Swing Rotor | 24×10/15ml                          | 4000r/min | RCF 2810×g |
| NO.4 Swing Rotor | 4×50ml                              | 4000r/min | RCF 2810×g |
| Timer Range      | 0~99min                             |           |            |
| Motor            | Microprocessor & Brushless DC motor |           |            |
| Noise            | ≤65dB(A)                            |           |            |
| Power Supply     | AC220V & 110V 50Hz 5A               |           |            |
| Dimension        | 520×395×395mm(L×W×H)                |           |            |
| Weight           | 29kg                                |           |            |