

# Certificate of Compliance



No. 3O190517.SLXDT22

Technical Construction File no. CE-2019-A0

Certificate's  
Holder:

Shanghai Lu Xiangyi Centrifuge Instrument  
Co., Ltd.

No.9, Lane 4390, Hunan Rd, Shanghai, 201318 China

Certification  
ECM Mark:



Product:

High-Speed Centrifuge, Large capacity  
refrigerated Centrifuge, Gel Card Incubator,  
Low-Speed Refrigerated Centrifuge, High-Speed  
Refrigerated Centrifuge, Low Speed Centrifuge

Model(s):

(see the following annex I)

Verification to:

Standard:

EN ISO 14971:2012, EN ISO 15223-1:2016,  
EN 1041:2013

related to CE Directive(s):

2014/35/EU (Low Voltage)

2014/30/EU (Electromagnetic Compatibility)

**Remark:** The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at [www.entecerma.it](http://www.entecerma.it). This Certificate of Compliance can be checked for validity at [www.entecerma.it](http://www.entecerma.it)

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the **CE** Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** and to perform all the necessary activities, as required by the Directive before placing the **CE** Mark on the product(s).

Date of issue 17 May 2019

Expiry date 16 May 2024

Chief Manager  
Marco Morino

Deputy Manager  
Amanda Payne

Ente Certificazione Macchine Srl

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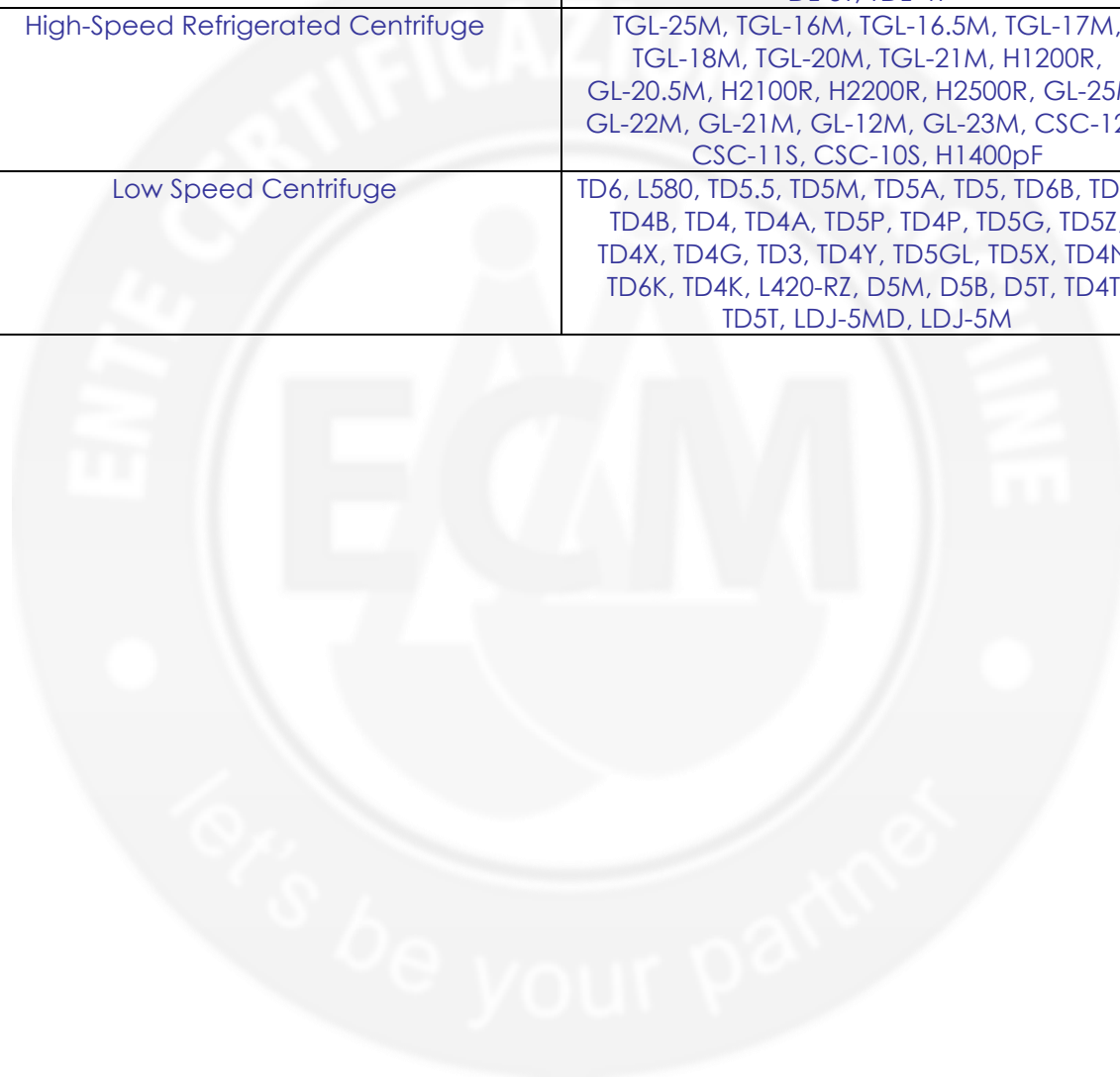
# Annex I

No. 3O190517.SLXDT22

Technical Construction File no. CE-2019-A0



| Product                                | Model   |
|--|---|
| High-Speed Centrifuge                  | TG20.5, TG19, TG18.5, TG16.5, TG16, TG16A, TG12X, TD10K   |
| Large capacity refrigerated Centrifuge | L800R, DL-8M, L600R, DL-6M, DL-5M   |
| Gel card incubator                     | F37-12X2  |
| Low-Speed Refrigerated Centrifuge      | TDL-5M, TDL-8M, L580R, DL-5B, DL-5T, TDL-5T, DL-5T, TDL-4T  |
| High-Speed Refrigerated Centrifuge     | TGL-25M, TGL-16M, TGL-16.5M, TGL-17M, TGL-18M, TGL-20M, TGL-21M, H1200R, GL-20.5M, H2100R, H2200R, H2500R, GL-25M, GL-22M, GL-21M, GL-12M, GL-23M, CSC-12S, CSC-11S, CSC-10S, H1400pF             |
| Low Speed Centrifuge                   | TD6, L580, TD5.5, TD5M, TD5A, TD5, TD6B, TD5B, TD4B, TD4, TD4A, TD5P, TD4P, TD5G, TD5Z, TD4X, TD4G, TD3, TD4Y, TD5GL, TD5X, TD4N, TD6K, TD4K, L420-RZ, D5M, D5B, D5T, TD4T, TD5T, LDJ-5MD, LDJ-5M |







# *Certificate of Quality Management System*

Certificate No.: 008314QR2

*Certified that*

**Shanghai Lu Xiangyi Centrifuge Instrument Co., Ltd.**

No.9, Lane 4390, Hunan Road, Zhoupu Town, Pudong New District, Shanghai, China

Unified Social Credit Code: 91310115755742061A

*Has established a Quality Management System which is in Accordance  
with the Requirements of the Standard:*

**GB/T 19001-2016/ISO 9001:2015**

**SCOPE OF CERTIFICATION**

**Production and Sales of Centrifuge**

*Expiry of Certificate for Last Cycle: Mar. 24, 2020*

*Validity of Certification: Apr. 3, 2020 To: Mar. 24, 2023*

*Effective Date of the Certificate: Apr. 3, 2020*

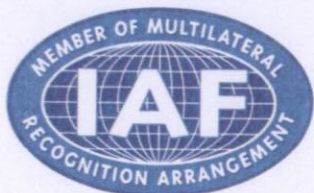
*(The effectiveness of this Certificate shall be validated by periodic surveillance audit of EWC for maintenance.*

*Conditions on effectiveness of certificate see <http://www.ewqcc.org> and official website of Certification and  
Accreditation Administration of People's Republic of China <http://www.cnca.gov.cn>*

*Expiry of This Certificate is Mar., 2021)*

Serial No.: YM046004

**EWC:**







ISTITUTO SERVIZI  
EUROPEI TECNOLOGICI

ISET S.r.l.

Sede Legale e Uffici

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[www.iset-italia.eu](http://www.iset-italia.eu) [iset@iset-italia.com](mailto:iset@iset-italia.com)

Cap. soc. i.v.

€ 10.200,00

Cod. Fisc. e P.IVA Reg. Imprese

02 332 750 369

REA

02 332 750 369

Cap. soc. i.v.

MN 0221098

## CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) **APPLICANT:** (who finally puts the product on the market)

Shanghai Lu Xiangyi Centrifuge Instrument Co., Ltd  
No.9, Lane 4390, Hunan Rd, Shanghai, 201318 China

- 2) **CERTIFICATE NO.:** I/SETC.001020190605

**FILE REFERENCE:** CE-2019-A0

- 3) **ISET MARK:**



- 4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):



The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- 5) **TYPE OF PRODUCT:** High-Speed Centrifuge, Large capacity refrigerated Centrifuge,

Gel Card Incubator, Low-Speed Refrigerated Centrifuge,

High-Speed Refrigerated Centrifuge, Low Speed Centrifuge

**MODEL(S):** See the following annex I

- 6) **LIST OF DIRECTIVES / REGULATIONS / STANDARDS** (as declared by the manufacturer itself)

In Vitro Diagnostic Directive (98/79/EC)

EN ISO 14971:2012, EN ISO 15223-1: 2016, EN 1041: 2013,

EN 61010-2-101:2002, EN 61010-1:2010, EN 61326-2-6:2006

- 7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website [www.iset-italia.eu](http://www.iset-italia.eu). This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.

- 8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

- 9) **DATE OF ISSUE:** 05/06/2019

**EXPIRY DATE:** 04/06/2024

- 10) **SIGNATURE:** Miriam Camplone

(On behalf of the Legal representative)



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**ISTITUTO SERVIZI  
EUROPEI TECNOLOGICI**

## ISSET S.r.l.

Sede Legale e Uffici

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Cap. soc. i.v.

€ 10.200,00

Cod. Fisc. e P.IVA Reg. Imprese

02 332 750 369

REA

02 332 750 369

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MN 0221098

# ANNEX I

High-Speed Centrifuge: TG20.5, TG19, TG18.5, TG16.5, TG16, TG16A, TG12X, TD10K

Large capacity refrigerated Centrifuge: L800R, DL-8M, L600R, DL-6M, DL-5M

Gel card incubator: F37-12X2

Low-Speed Refrigerated Centrifuge: TDL-5M, TDL-8M, L580R, DL-5B, DL-5T,

TDL-5T, DL-5T, TDL-4T

High-Speed Refrigerated Centrifuge: TGL-25M, TGL-16M, TGL-16.5M, TGL-17M, TGL-18M,

TGL-20M, TGL-21M, H1200R, GL-20.5M, H2100R,

H2200R, H2500R, GL-25M, GL-22M, GL-21M, GL-12M,

GL-23M, CSC-12S, CSC-11S, CSC-10S, H1400pF

Low Speed Centrifuge: TD6, L580, TD5.5, TD5M, TD5A, TD5, TD6B, TD5B, TD4B, TD4,

TD4A, TD5P, TD4P, TD5G, TD5Z, TD4X, TD4G, TD3, TD4Y,

TD5GL, TD5X, TD4N, TD6K, TD4K, L420-RZ, D5M, D5B,

D5T, TD4T, TD5T, LDJ-5MD, LDJ-5M





This is to certify that the Quality Management System of

## Shanghai Lu Xiangyi Centrifuge Instrument Co., Ltd.

Unified Social Credit Code : 91310115755742061A

Operation Address : No.9, Lane 4390, Hunan Road, Zhoupu Town, Pudong New District, Shanghai, China

Registered Address : No.9, Lane 4390, Hunan Road, Zhoupu Town, Pudong New District, Shanghai, China

applicable to

Manufacture and sales of low speed centrifuge, large capacity refrigerated centrifuge, low speed refrigerated centrifuge, high speed centrifuge, high speed refrigerated centrifuge (within the scope of license qualification)

has been assessed and registered by NQA against the provisions of

### ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



015

Certificate Number

**46701**

Date:

22 July 2019

Valid Until:

22 July 2022

EAC Code:

19

