



Hunan Kecheng Instrument Equipment Co.,Ltd

EC Declaration of Conformity

Brand Name : *Kecheng*

Product Name : *Centrifuge*

Model Number : *2-4,GT116C*

We hereby confirm that these products have already past all the test under the European

98/79/EC

EN 61326-1:2013

EN61326-2-6:2013

Standard(s)

EN 61010-1:2010+A1:2019

EN 61010-2-101:2017

EN 61326-1:2013

EN 61326-2-6:2013

Manufacturer name & adress-----

Hunan Kecheng Instrument Equipment Co.,Ltd

NO.602,6F,C2 Building, JinRong Wangcheng Sci-Tech Industrial Park,NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone , Changsha city.Hunan province,China

The Certificate of Conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production.

SALES DIRECTOR :Amy Liu

DATE OF ISSUE :18th,Jan 2022

DATE OF SIGNATURE :29th,June 2024

Hunan Kecheng Instrument Equipment Co.,Ltd





Test Verification of Conformity

Certificate No.: CTSE21120026

Date: 2022-01-18

In accordance with the following Applicable Directives:

98/79/EC

In vitro diagnostic medical devices

The equipment, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

EN 61010-1: 2010+A1: 2019

EN 61010-2-101: 2017

The test results are traceable to the international or national standards.

Applicant: **Hunan Kecheng Instrument Equipment Co., Ltd**
NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

Manufacturer: **Hunan Kecheng Instrument Equipment Co., Ltd**
NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

EUT Name: **Centrifuge**

Model number: **GT116A**

Listed Model(s): GT216C,GT318C,GT320C,GT420C,GT116C,GTR216C,W3-16R,GTR318C,GTR320C,GTR420C,4-25R,4-30R,GTR116C,GR16C,DT35C,DT36C,DT45C,DT46C,2-6C,2-5C,DTR35C,DTR36C,DTR45C,DTR46C,GDR421C,GDR521C,GDR525C,GDR610C,RG16D,DDR6C,DD6C,DDR72C,WK96C,TDL5Y, Super MiniStar, 2-4, Ministar, MiniStar Plus ES-6T, GT318A, DR5D, DR5, 4-5N, 5-5N, KC-48, KC-48R, L3-5KM, L4-5KM, TD4M H2-12K, TD4X, TD4K, TD4B, TD4K_v2, 3-5N, TD5B, L4-4F, ZL3, TD4, DR3C, GTR320A DT45A, DTR45A, GT420A, GTR420A, GDR421A, GDR521A, GTR318A, GT320A, 1-16 1-16R, 3-18, 3-18R, 3-20, 3-20R, 4-5, 4-5R, 4-20, 4-20R, 4-21R, 5-21R, GT116A, GTR116A 2-6A, DT35A, 7-72R, TD5Z, DDR72A, Minimax 17, ZL2E, ZL2F, ZL2G, ZL3-1K, ZL3-2K ZL3-3K, GDR610A, DDR5A, DD5A, D3L, ZL3A

Laboratory: **Shenzhen Huatongwei International Inspection Co., Ltd.**
1/F, Bldg 3 and Bldg 9, Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China

Tel: 86-755-26715499

E-mail: cs@szhtw.com.cn

Website: Http://www.szhtw.com.cn

Note:

The certification is only valid for the equipment and configuration described, in conjunction with the test data detailed above.

The CE mark as shown beside can be used, under the responsibility of the manufacturer, after completion of an EC Directive of Conformity and compliance with all relevant EC Directive.



For and on behalf of

Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:

Caroline li





HTW

Test Verification of Conformity

Certificate No.: CTEE22010152

Date: Feb. 14, 2022

The equipment, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

EN 61326-1: 2013

EN 61326-2-6: 2013

The test results are traceable to the standards.

Applicant: Hunan Kecheng Instrument Equipment Co., Ltd

NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

Manufacturer: Hunan Kecheng Instrument Equipment Co., Ltd

NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

EUT Name: Centrifuge

Model number: GT116A

Listed Model(s): GT216C,GT318C,GT320C,GT420C,GT116C,GTR216C,W3-16R,GTR318C,GTR320C,GTR420C,4-25R,4-30R,GTR116C,GR16C,DT35C,DT36C,DT45C,DT46C,2-6C,2-5C,DTR35C,DTR36C,DTR45C,DTR46C,GDR421C,GDR521C,GDR525C,GDR610C,RG16D,DDR6C,DD6C,DDR72C,WK96C,TDL5Y, Super MiniStar, 2-4, Ministar, MiniStar Plus ES-6T, GT318A, DR5D, DR5, 4-5N, 5-5N, KC-48, KC-48R, L3-5KM, L4-5KM, TD4M H2-12K, TD4X, TD4K, TD4B, TD4K_v2, 3-5N, TD5B, L4-4F, ZL3, TD4, DR3C, GTR320A, DT45A, DTR45A, GT420A, GTR420A, GDR421A, GDR521A, GTR318A, GT320A, 1-16 1-16R, 3-18, 3-18R, 3-20, 3-20R, 4-5, 4-5R, 4-20, 4-20R, 4-21R, 5-21R, GT116A, GTR116A 2-6A, DT35A, 7-72R, TD5Z, DDR72A, Minimax 17, ZL2E, ZL2F, ZL2G, ZL3-1K, ZL3-2K ZL3-3K, GDR610A, DDR5A, DD5A, D3L, ZL3A

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Tel: 86-755-26715499

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Note:

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For and on behalf of

Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:





QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. 117 22 QU 0038-03 R1S

This is to certify that

**Hunan Kecheng Instrument
Equipment Co., Ltd**

Unified social credit code 91430122MA4L2RPG8B

Location

No. 602, 6F, C2 Building, Jinrong Wangcheng
Sci-Tech Industrial Park, No. 858 Purui West Road,
Wangcheng Economic & Technological
Development Zone, Changsha City, Hunan Province

has been assessed and registered as meeting the requirements of

GB/T19001-2016/ISO9001:2015

Scope of approval

**Production and Sales of Centrifuges within the
Scope of Medical Device Record-filing Certificate**

Signed by:



First Certification: 27 Mar. 2019

Recertification Date: 03 Mar. 2022

Expiry Date: 26 Mar. 2025

Shanghai Ingeer Certification Assessment Co., Ltd.

Certification and Accreditation Administration of PRC: CNCA-R-2003-117

Tel: 400-182-9001/+86 21-51114700

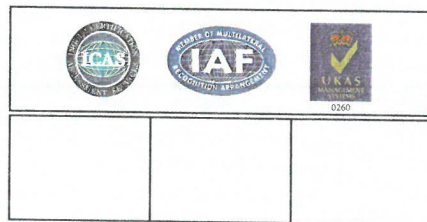
Web: www.icas.org.cn

Add: Room 801, HuaDing Mansion, 2368# West Zhongshan Rd.,

Xuhui District, Shanghai, China, 200235



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First Surveillance Audit

Second Surveillance Audit

Third Surveillance Audit

The ownership of the certificate belongs to Shanghai Ingeer Certification Assessment Co., Ltd. The information & validation of this certificate can be checked on the CNCA website: WWW.CNCA.GOV.CN and ICAS website, or by calling ICAS's clients services Dept. The certificate is only valid when used together with related permits when appropriate. If the organization can't effectively maintain the above management system, ICAS has the right to withdraw the qualification certificate.



MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. 117 22 QOM 0022 RTS

This is to certify that **Hunan Kecheng Instrument Equipment Co., Ltd**

Unified social credit code 91430122MA4L2RPG8B

Location **No. 602, 6F, C2 Building, Jinrong Wangcheng Sci-Tech Industrial Park, No. 858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha City, Hunan Province**

has been assessed and registered as meeting the requirements of

ISO13485:2016

Scope of approval **Production and Sales of Centrifuges within the Scope of Medical Device Record-filing Certificate**

Signed by: _____



First Certification: 27 Mar. 2019
 Recertification Date: 03 Mar. 2022
 Expiry Date: 26 Mar. 2025

Shanghai Ingeer Certification Assessment Co.,Ltd.

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Certification No. 117 22 QOM 0022 RTS

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Scope of approval **Production and Sales of Centrifuges within the Scope of Medical Device Record-filing Certificate**

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