



# HTW

## 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

**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](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

**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:**

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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](http://www.icas.org.cn)  
 Add: Room 801, HuaDing Mansion, 2368# West Zhongshan Rd., Xuhui District, Shanghai, China, 200235



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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](http://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 Q0M 0022 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

**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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