

## ***Declaration of Conformity***

**Manufacturer:** Jiangsu Huida Medical Instruments Co., Ltd.  
**Address:** Qingfeng Industrial Park, Yandong, Yancheng City, Jiangsu Province, P. R. China  
*whose single Authorized* Name: Riomavix S.L.  
**EU-Representative:** Address: Calle de Almansa 55, 1D, Madrid 28039 Spain  
**Product Name:** Laboratory Plasticwares

**Classification:** IVDR/Class A

We hereby declare under the sole responsibility of the manufacturer that:  
Those above products with CE marking which are manufactured by our company all comply with EU in Vitro Diagnostic Regulation IVDR 2017/746, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

### **General applicable directives:**

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

### **Directive we are following:**

European Union Committee in Vitro Diagnostic Regulation IVDR 2017/746

**Signature:** Aibing Cao  
**Title:** Manager  
**Position:** Yancheng, Jiangsu  
**Date:** 2024.05.24





# Certificate

## ISO 13485 : 2016

### Yancheng Huida Medical Instruments Co., Ltd

No.2 Kuiyuan Road, Xuefu Town, Yandu District, Yancheng City,  
Jiangsu Province, 224035, P.R.China

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

### SCOPE

Design and development, manufacture, sales and distribution of:

Absorbable sutures with or without needle, Nonabsorbable sutures with or without needle, Disposable Sterile Blood Lancets, Disposable Surgical Blades (with and without handle), Disposable Blood Collection Tubes, Microcentrifuge tubes, Slide Storage Boxes, Embedding Cassettes, Slide Mailers, Microscope Slides, Microscope Cover Slips, Transport Swabs with medium and without medium, Disposable collection swab, Vaginal speculums, Identification bracelets, Cervical Scraper and brush, Amniotic membrane perforators, Urine bag, Umbilical cord clamps, Capillary Tube, Disposable pap smear kit, Disposable Safety Scalpel.

Sales and distribution of:

Tourniquet, Non vacuum tube, Needle holder, Blood collection needle, Multi-Samples Needle, Butterfly needles, Luer adapter, Disposable Medical Mask, Disposable surgical face mask, Inoculation Loop, Petri dish, Robotic tips, Pipette tips, Deep well plates, PCR plates, PCR tubes, PCR strips, Serological pipette, Elisa plate, Cuvette, Cryovials, Virus collection and transport kits, Reagent Reservoirs, Specimen Containers, Pasteur Pipettes, Centrifuge Tubes, Plastic Test Tube, Cell Spreader, Culture Plate, Pipette Tip Boxes, PCR plate sealing film, PCR tube rack, ESR tube, Test Tube Stopper, Test Tube Racks, Centrifuge tube Boxes, Virus Transport Tube, Surgical Needle (sterile and non-sterile), Alcohol swabs, Blood counting chamber, Specimen Bag, Pipette,

Biohazard Bag.

GROUP CODE

A - D - F

<b>Certificate No</b>	: TC-75513
<b>Registration Date</b>	: 28.07.2022
<b>Reissue Date</b>	: 29.07.2024
<b>Expiry Date</b>	: 27.07.2025
<b>Certificate Period</b>	: 3 Years (From the date of registration)
<b>Exclusion</b>	: 7.5.3 / 7.5.4

  
PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal / İSTANBUL  
Tel: +90 216 510 63 48 - 49 Pbx Faks: +90 216 517 63 49  
www.pca-tr.com info@pca-tr.com



ACCREDITED

Management  
Systems  
Certification Body

MSCB-103



Kaixin Certification (Beijing) Co.,Ltd.  
**Certificate of Registration**

Registration No. : 626022Q10066R1

*This is to certify that*

***Jiangsu Huida Medical Instruments Co.,Ltd***

Unified Social Credit Code:91320902753918190F

Registration/Headquarters/Production address: Qingfeng Village West Park of  
Southeast Industrial Park Yandong Town Tinghu District Yancheng City Jiangsu  
China.

Branch production address 1 (Laboratory Glassware): East head of Peiliu Renmin  
Road, Lugou Town, Jianhu County, Yancheng City Jiangsu China.

Branch production address 2 (Plastic Labware): 2 Kuijuan Road, Xuefu Town,  
Yandu District, Yancheng City Jiangsu China.

*The Management system is in conformity with*

**GB/T19001-2016 / ISO9001:2015 standard**

***Scope: Manufacture and sales of microscope slides, cover glass  
and laboratory glassware and plastic labware***

Reissue Date : 2022-09-06

Term of Validity : 2025-09-08

First Issue Date : 2019-09-10

**NOTE:**The certified organization must accept the surveillance audit duly, and the audit shall be approved as effective before approving that this certificate can maintain as valid. On and by 2023-09-07, this certificate shall be used together with notice of maintaining certification and registration.



本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询或登陆公司网站www.kcb-china.com进行查询; 也可通过电子邮件kcb@kcb-china.com进行确认。本证书在国家规定的各行政、资质许可范围及有效期内使用有效。

Users can logon www.cnca.gov.cn or www.kcb-china.com to check the certificate status, to confirm by means of kcb@kcb-china.com to check the certificate status, to confirm by means of kcb@kcb-china.com. This certificate should be used under national specified administrative qualification licence scope and within the expiration date.

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