



This is to certify that the Quality Management System of

## Zhejiang Zhongfan Medical Technology Co., Ltd.

Unified Social Credit Code : 91330782MA28ECRC78

Operation Address : No.968, Xuefeng West Road, Beiyuan Street, Yiwu City, Zhejiang Province, China

Registered Address : No.968, Xuefeng West Road, Beiyuan Street, Yiwu City, Zhejiang Province, China

applicable to

Production and sales of Liquid Wound Dressings (within the scope of qualification)  
and Medical Laboratory Consumables (Pipetting Tips)

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



Certificate Number

46437

Date:

28 May 2019

Valid Until:

28 May 2022

EAC Code:

04/14







## QUALITY MANAGEMENT SYSTEM CERTIFICATION

Registration NO. Q15280ROS265024

We hereby certify that the organization :

**ZHEJIANG ZHONGFAN MEDICAL TECHNOLOGY CO., LTD**

Unified social credit code : 91330782MA28ECRC78

Is in conformity with Management System Standard:

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

The certificate is valid to the following product(s)/service:

Design, development, production and sales of injection molding process series products and extrusion process series products; design, development, production and sales of laboratory consumables (pipette, centrifuge tube, PCR plate, etc.); design, development, production and sales of disinfection and anti (bacteriostatic) agents; design, production and sales of class I, II and III medical device products

Registered Address/Business Address: NO.968, WEST  
XUEFENG ROAD, BEIYUAN, YIWU, ZHEJIANG, CHINA

Date of issue : 11-05-2020    Date of expiry : 10-05-2023

The validity of this certificate is maintained in accordance with the regular supervision of the issuing authority. For certificate validity information, please visit [www.china-ukas.cn](http://www.china-ukas.cn)



Public notice (annual review)

**Kanlun International Quality Certification Service (China) Co., Ltd.**

<http://www.china-ukas.cn>





## OCCUPATION HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATE

Registration NO. S15280ROS265024

We hereby certify that the organization :

**ZHEJIANG ZHONGFAN MEDICAL TECHNOLOGY CO., LTD**

Unified social credit code : 91330782MA28ECRC78

Established occupational health and safety  
management system meets standards

**GB/T45001-2020 idt ISO45001: 2018**

The certificate is valid to the following product(s)/service:

Occupational health and safety management activities involved in the design, development, production and sales of injection molding process series products and extrusion process series products; design, development, production and sales of laboratory consumables (pipette, centrifuge tube, PCR plate, etc.); design, development, production and sales of disinfection and anti (bacteriostatic) agents; design, production and sales of class I, II and III medical device products

Registered Address/Business Address: NO.968, WEST  
XUEFENG ROAD, BEIYUAN, YIWU, ZHEJIANG, CHINA

Date of issue : 11-05-2020    Date of expiry : 10-05-2023

The validity of this certificate is maintained in accordance with the regular supervision of the issuing authority. For certificate validity information, please visit [www.china-ukas.cn](http://www.china-ukas.cn)



Public notice (annual review)

**Kanlun International Quality Certification Service (China) Co., Ltd.**

<http://www.china-ukas.cn>





# ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

Registration NO. E15280ROS265024

We hereby certify that the organization :

**ZHEJIANG ZHONGFAN MEDICAL TECHNOLOGY CO., LTD**

Unified social credit code : 91330782MA28ECRC78

Is in conformity with environmental management system standard:

**GB/T24001-2016 idt ISO14001:2015**

The certificate is valid to the following product(s)/service:

Environmental management activities in the design, development, production and sales of injection molding process series products and extrusion process series products; design, development, production and sales of laboratory consumables (pipette, centrifuge tube, PCR plate, etc.); design, development, production and sales of disinfection and anti (bacteriostatic) agents; design, production and sales of class I, II and III medical device products

Registered Address/Business Address: NO.968, WEST  
XUEFENG ROAD, BEIYUAN, YIWU, ZHEJIANG, CHINA

Date of issue : 11-05-2020 Date of expiry : 10-05-2023

The validity of this certificate is maintained in accordance with the regular supervision of the issuing authority. For certificate validity information, please visit [www.china-ukas.cn](http://www.china-ukas.cn)



Public notice (annual review)

**Kanlun International Quality Certification Service (China) Co., Ltd.**

<http://www.china-ukas.cn>





## CERTIFICATE OF FDA REGISTRATION

**Fiscal Year 2020**

**Dear Official Correspondent:**

This document provides notification of the registration numbers assigned to your establishment:

**Establishment Detail:**

Registration Number: 3015007522

Owner/Operator Number: 10058633

Establishment &  
Owner/Operator: ZHE JIANG ZHONGFAN MEDICAL  
TECHNOLOGY CO., LTD

No. 968 West Xuefeng Road, Beiyuan, Yiwu, Zhejiang  
322000, CHINA

Business Type: Manufacturer and Exporter

US Agent: Thomas Weast

6430 Baum Dr, Knoxville, Tennessee, 37919

**Memos:**

1) The user can browse the registration information through the following web page:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>



*Thomas E. Weast*

Thomas E. Weast, P.E.

Executive Director

Shanghai CV Certification Technology Co., Ltd.

[www.ceve.org.cn](http://www.ceve.org.cn) & [www.fda-cv.com](http://www.fda-cv.com)



## CERTIFICATE OF FDA REGISTRATION

**Fiscal Year 2020**

**Device Listing Numbers & Device Names & Product Codes:**

D250471	Liquid wound dressing	NAC
D375355	Medical face shield; Medical safety goggles	LYU
D377556	Alcohol prep pad	LRJ



*Thomas E. Weast*

Thomas E. Weast, P.E.  
Executive Director  
Shanghai CV Certification Technology Co., Ltd.  
[www.ceve.org.cn](http://www.ceve.org.cn) & [www.fda-cv.com](http://www.fda-cv.com)





## Compliance Report

**Applicant:** Zhejiang Zhongfan Medical Technology Co., Ltd  
**Address:** No. 968 Xuefeng West Road, Beiyuan Subdistrict,  
Yiwu, Zhejiang, China  
**Product:** Pipette Tip, Pipette Tips Box, Transfer Pipette, Centrifuge Tube, Urinary  
Sediment Tube, Centrifuge Tube Rack, PCR Plate, Sealing Film, Funnel,  
Cryo Tube ( Freezing Tube), Petri Dish, Culture Plate, Specimen  
Container (Urine Cup , Stool Cup, Sputum Cup, Culture Tube), Test Tube,  
Test Tube Stopper, Test Tube Rack, Elisa Plate, Microscope Slides,  
Microscope Cover Glass, Slide Storage Box, Embedding Cassettes,  
Reagent Bottles, Cryo (Freezing)Box  
**Type:** See Annex of details

**The submitted technical files including test report of the above products  
have been reviewed against the self declaration requirements of conformity  
for CE marking according to IVDD (In Vitro Diagnostic Directive,  
98/79/EC).**

The review result of the technical files and test report support the self declaration for  
the devices listed above. The test report and the technical files are the annex of this  
report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must  
ensure that all the requirements of the appropriate EU directive(s) have and continue  
to be met.

No. **EU080008**

Issue Date: **Aug. 21 2018**

General Manager (Signature)



This report is the property of POSI and should be returned to POSI upon request. Whenever the devices listed in this  
Report were changed or the directive/standards were changed, this report shall be reissued.

# POSI

## ANNEX

Name	Type
Pipette Tip	10ul, 20ul, 100ul, 200ul, 250ul, 300ul, 500ul, 1000ul, 5ml, 10ml
Pipette Tip Box	10ul, 100ul, 200ul, 300ul, 1000ul, 5ml, 10ml
Transfer Pipette	0.2ml, 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml
Centrifuge Tube	0.1ml, 0.2ml, 0.5ml, 1.5ml, 2ml, 5ml, 7ml, 10ml, 15ml, 25ml, 50ml, 100ml, 120ml
Urinary Sediment Tube	12ml
Centrifuge Tube Rack (Box)	0.2ml, 0.5ml, 1.5ml, 2ml, 3ml, 5ml, 7ml, 10ml, 15ml, 25ml, 50ml, 21-place, 24-place, 28-place, 32-place, 40-place, 44-place, 49-place, 50-place, 60-place, 72-place, 80-place, 90-place, 96-place, 100-place
PCR Plate	96-well, Flat, Convex, Skirted
Sealing Film	Transparent, Aluminum, Strong Breathable
Funnel	match with centrifuge tube: 10ml, 15ml
Cryo Tube (Freezing Tube)	0.5ml, 1.5ml, 1.8ml, 2ml, 4ml, 5ml, 7ml, 10ml
Petri Dish	35mm, 60mm, 70mm, 90mm, 90mm-2 section, 90mm-3 section, 90mm-4 section, 100mm, 120mm, 150mm, 10*10cm, 12*12cm, 13*13cm, 25*25cm
Culture Plate	Culture Plate
Specimen Containers	Urine Cup: 10ml, 20ml, 25ml, 30ml, 40ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml, 250ml, 500ml; Stool Cup: 25ml, 30ml, 40ml, 60ml, 100ml, 120ml; Sputum Cup 20ml; Culture Tube 25ml
Test Tube	12*100mm, 12*60mm, 3ml, 12*75mm, 5ml, 12*100mm, 13*78mm, 13*100mm, 15*95mm, 15*96mm, 15*100mm, 16*100mm, 16*150mm, 20*130mm
Test Tube Stopper	12mm, 13mm, 15mm, 16mm, 20mm, 25mm



# POSI

Test Tube Rack	Round Holes, Square Holes, 12mm, 13mm, 15mm, 16mm, 17mm, 20mm, 25mm
Elisa Plate	96-well, 8-well*12, 12-well*8
Microscope Slides	Plain, Single Frosted, Double Frosted, Color Coat, Standard Microscope Slide, Adhesion Slides, PCB, PCC, PCI, Blood Smear, LCB, Mega-Sized
Microscope Cover Glass	<p>Standard Cover Glass: 18*18, 20*20, 22*22, 24*24, 22*32, 24*32, 22*40, 24*40, 22*50, 24*50, 24*55, 22*60, 24*60</p> <p>High borosilicate: 18*18, 20*20, 22*22, 24*24, 22*32, 24*32, 22*40, 24*40, 22*50, 24*50, 24*55, 22*60, 24*60</p> <p>Circular: φ 8, φ 10, φ 11, φ 12, φ 13, φ 14, φ 15, φ 16, φ 18, φ 20, φ 22</p> <p>Hemacytometer: 20*26, 22*22, 24*24</p>
Slides Storage Box	1slot, 2slot, 3slot, 5slot, 10slot, 12slot, 20slot, 25slot, 50slot, 100slot
Embedding Cassettes	Biopsy Processing, Tissue Processing
Reagent Bottle	50ml, 100ml, 250ml, 500ml, 1000ml, 2000ml, 3000ml, 5000ml, 10000ml, 20000ml
Cryo Box (Freezing Box)	10-place, 16-place, 25-place, 36-place, 49-place, 50-place, 81-place, 96-place, 100-place

END OF THE ANNEX