



EBO

CERTIFICATE OF CONFORMITY

No.: EBO1808103-V271

The following product has been tested by us with the listed standards and found in conformity with the European directive EMC 2014/30/EU, LVD 2014/35/EU and IVD 98/79/EC.

Applicant: ZENITH LAB (JIANGSU) CO., LTD

Address: No.12, Hongshan Road, Jincheng Industrial Area, Jintan District, Changzhou, Jiangsu Province, China

Manufacturer: ZENITH LAB (JIANGSU) CO., LTD

Address: No.12, Hongshan Road, Jincheng Industrial Area, Jintan District, Changzhou, Jiangsu Province, China

EUT: CENTRIFUGE

Brand Name: Zenith, Zhengji

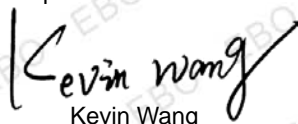
Model No. : 80-2C, LC-04R-N, LC-04R, LC-04S, LC-04A, LC-04B, LC-04C, LC-04L, LC-04P, LC-04P-L, LC-04M, TDL-4A, TDL-4C, LC-05A, LC-05B, LC-05C, TDL-5A, LC-06C, TDL-6C, HC-12A, HC-12C, HC-16A, HC-16B, HC-16C, HC-16L, HC-20L, HC-20C, LC-04F, LC-05F, LC-06F, HC-16F, HC-16F, HC-20F, MC-04, MC-07, MC-10, MC-12, MCKD-05, MCKD-07, LC Series, TDL Series, HC Series, MC Series, MCKD Series, ZJ Series, FibrinFUGE²⁵

Test Report No.: EBO1808103-E269, EBO1808103-E270

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards: EN 61326-1:2013
EN 61326-2-6:2013
EN 61010-1:2010
EN 61010-2-101:2017

The test report was carried out from submitted type samples of a product in conformity with the specification of the respective standards. The CE mark as shown below can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of Conformity and compliance with all relevant EC Directives.


Kevin Wang

Laboratory Manager

Issue Date: August 27, 2018



Due Date: August 26, 2021

Shenzhen EBO Testing Center

A506, Financial port building, Xin'an Sixth Road, 82th District, Bao'an, Shenzhen, China.

Tel: 86-755-33126608 ebo@ebotest.com www.ebotest.com



MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 19 QOM 0008 R1S

This is to certify the quality management systems of

Zenith Lab (Jiangsu) Co., Ltd.

Unified Social Credit Code **91320413720511570J**

Location **No. 12 Hongshan Road, Industrial Park, Jincheng Town, Jintan District, Changzhou, Jiangsu**

has been assessed and registered as meeting the requirements of ISO13485: 2016 <Medical device-Quality management systems - Requirements for regulatory purposes>

Scope of approval

Design, Production and Sales of Medical Centrifuge and Bio-filler Plasma Gel, Automatic Steel Sterilizer

Signed by:



First Certification: 28 Jul. 2016

Recertification Date: 15 Jan. 2019

Expiry Date: 27 Jul. 2022

Revision Date: 06 Dec. 2019

Shanghai Ingeer Certification Assessment Co.,Ltd.

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

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

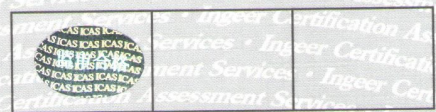
Web: www.icas.org.cn

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

Xuhui District, Shanghai, China, 200235



Focus on icas WeChat platform



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.



CERTIFICATE OF FDA REGISTRATION

This certifies that:

ZENITH LAB (JIANGSU) CO.,LTD

No.12 Hongshan RD, Jincheng Industrial Area,
Jintan Changzhou Jiangsu, China 213200.

Is registered and has listed the following device with the U.S.Food and Drug Administration
for FY 2018 pursuant to Title 21,807 et seq.of the United States Code of Federal Regulations:

Establishment Registration:	3014060475
Device Classification Name:	CENTRIFUGE (MICRO,ULTRA,REFRIGERATED) FOR CLINICAL USE
Product Code:	JQC
Regulation Number:	862.2050
Facility Name:	Zenith Lab (Jiangsu) Co.,Ltd
Address:	No.12 Hongshan RD, Jincheng Industrial Area, Jintan Changzhou Jiangsu, China 213200.
Registration Satatus:	Active

This U.S.Food and Drug Administration does not issue a certificate of registration,nor does the U.S.Food and Drug Administration recognize a certificate of registration.



FDA U.S. FOOD & DRUG
ADMINISTRATION