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Date: 2021.07.03 11:03:40 EEST
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CERTIFICATE

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, FibrinFUGE^{25}
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

CE

SHENZHEN EBO TESTING CENTER CERTIFICATE

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

INGEER CERTIFICATION ASSESSMENT SERVICES

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 19 Q0M 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

First Surveillance Audit | Second Surveillance Audit | Third Surveillance Audit

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 Titile 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