

Verification of Compliance



No. EC.1282.0A140311.WHH0789

Certificate's Holder: ZENITH LAB(JIANGSU)CO.,LTD

No.12,Hongshan Road,Jincheng Industrial Area,
Jintan,Jiangsu,China

Product: STEAM STERILIZERS

Model(s): LDZX-40(50 75 100 150)B(BD)(BP)
DGL-30(35 40 50 60 75 80 100)A(B G1 G2)
DGS-280(A B C A+ B+ C+)B8C,B12C,B16V
B18C,B23C,B8C-V,B18C-V,B23C-V,B45C-V

Directives: 93/42/EEC Medical devices

Standards: EN 13060:2014 EN 61010-1:2010
EN 60601-1-2:2015 EN ISO 14971:2012

Remark: This Verification of Compliance has been issued on a voluntary basis. ECM confirms that a Technical Construction File (TCF) is existent for the above listed product(s). The TCF satisfactorily covers the essential requirements of the above listed Directive(s).

Other relevant Directives have to be observed in case they are applicable.

This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above. Whereas the Manufacturer is responsible of the certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible of the internal production control to ensure the product(s) are in compliance with the essential requirements of the above mentioned Directive(s).

This certificate can be checked for validity at www.entecerma.it

Date of issue MARCH 2016

Certification Chief Manager

Tim Mahan



Expiry date MARCH 2023

Certification Deputy Manager

Viola Moller





MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 19 QU 0030-12 R15

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
GB/T19001-2016/ISO9001:2015

Scope of approval

lab instruments (stirrer series, shaker series, water bath series, oven series, incubator series, refrigerator series, bio-filler plasma gel series) and medical centrifuge design and production distiller

Signed by:



First Certification: 28 Mar. 2017
Recertification Date: 04 Dec. 2019
Expiry Date: 27 Mar. 2023
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, 2388# West Zhongshan Rd., Xuhui District, Shanghai, China, 200235



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First Surveillance Audit

Second Surveillance Audit

Third Surveillance Audit

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.