

Registration No. 07619Q1811R0S-SD/00



# QUALITY MANAGEMENT SYSTEM CERTIFICATE

The certificate information is available on the CNCA of the official website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

**This is to certify that the quality management system of  
EASYSEAL MEDICAL TECHNOLOGY CO., LTD.**

Uniform Code of Social Credit:91370303556745059X

Reg Add: 150 METERS SOUTH EAST, DING ZHUANG ROAD DEVELOPMENT ZONE AND NORTH ROAD INTERSECTION, HIGH TECH ZONE, ZIBO, SHANDONG  
Pro Add: 150 METERS SOUTH EAST, DING ZHUANG ROAD DEVELOPMENT ZONE AND NORTH ROAD INTERSECTION, HIGH TECH ZONE, ZIBO, SHANDONG

**Which is in conformity with  
GB/T19001-2016/ISO9001:2015  
This certificate covers the following scope of**

Sales of medical devices within the scope of licensing; Design, production and sale of medical sealing machines and medical insulation detectors

This certificate will not remain valid unless and until the certified customers accepts at least once surveillance audit annually within the validity period of the certificate and the surveillance audit conforming mark is affixed to the designated place on the certificate. Please login into [www.zrxbj.com](http://www.zrxbj.com) for this certificate's validity status.

Issue Date: 07. 10. 2019

Expiration Date: 07. 09. 2022

Beijing ZhongRunXing Certification Co., Ltd.

No. 804 Office No. 4 Building No. 12 Tu Cheng Road East,  
He ping Street Chaoyang District, Beijing

Issued by:

*XR Zhang*



中国认可  
国际互认  
管理体系  
MANAGEMENT SYSTEM  
CNAS C076-M





# CERTIFICATE

## ATTESTATION CERTIFICATE OF MACHINERY AND ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been inspected and audit has been completed successfully.

2006/42/EC Machinery Directive 2014/30/EU Electromagnetic Compatibility Directive and 2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name : **Easysael Medical Technology Co., Ltd.**

Company Address : East of the Cross of Luxin Road and Dingzhuang Road, High-tech District, Zibo, Shandong, China

Related Directives and Annex : **2006/42/EC Machinery Directive**  
**2014/35/EU Low Voltage Directive**  
**2014/30/EU Electromagnetic Compatibility Directive**

Related Standards : **EN ISO 12100:2010, EN 60204-1:2018, EN 61000-6-3:2007**  
**EN 61000-6-1:2007, EN 61000-3-2:2014, EN 61000-3-3:2013**

Product Name : **Heat Sealer**

Report No and Date : **NIU-CE2292A0916766**

Product Brand/Model/Type : **EFOXY(X=0-9;Y=0-9)\EFOXY(X=0-9;Y=0-9)-(A\B);**  
**EF1XY(X=0-9;Y=0-9)-(a\ab);**  
**EF2XY(X=0-9;Y=0-9)\EF2XY(X=0-9;Y=0-9)-(A\B);**  
**EF3XY(X=0-9;Y=0-9)\EF3XY(X=0-9;Y=0-9)-(A\B);**  
**EF6XY(X=0-9;Y=0-9)\EF6XY(X=0-9;Y=0-9)-(A\B);**  
**EF8XY(X=0-9;Y=0-9)\EF8XY(X=0-9;Y=0-9)-(A\B); (a=A-Z;b=A-Z)**

Certificate Number : **M.2019.206.C2830**

Initial Assessment Date : **17.09.2019**

Registration Date : **18.09.2019**

Reissue Date/No : **-**

Expiry Date : **17.09.2024**

  
UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr). The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be notified in case of any changes on the product(s)

Address: **Mutlukent / Tahalleşi 2073 Sokak [Eski 93 Sokak] No:10 Çankaya – Ankara – TURKEY**  
Phone: **+90 0312 443 03 90** Fax: **+90 0312 443 03 76**  
E-mail: **info@udemtd.com.tr** [www.udem.com.tr](http://www.udem.com.tr)





# MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. 117 21 QOM 0059 ROS

This is to certify that **Easyseal Medical Technology Co., Ltd**

Unified social credit code 91370303556745059X

Location No. 6199, Qihuan Road, High-tech District, Zibo, Shandong

has been assessed and registered as meeting the requirements of

## ISO13485:2016

Scope of approval **Production of Medical Sealing Machine, Seal Strength Tester, Insulation Tester**

First Certification: 25 Mar. 2021

Expiry Date: 24 Mar. 2024

Signed by: \_\_\_\_\_



Shanghai Ingeer Certification Assessment Co., Ltd.

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

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

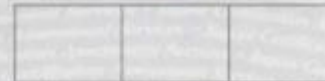
Web: www.icas.org.cn

Add: Room 601, HuaDing Mansion, 2368F West Zhongshan Rd.,

Kuhai District, Shanghai, China, 200235



Focus on our WeChat platform



First Seal/Issue Audit

Second Seal/Issue Audit

Third Seal/Issue 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.