

## 贵溪市金龙纹绣器材厂

### 环氧乙烷灭菌过程记录 Ethylene Oxide Sterilization Process Record

灭菌机编号 Sterilizer:

灭菌批号 Sterilization Batch:

2018081101

日期 Date:

20180811

班次 Order:

1

Article Name物品名称	Lot No.生产批号	Specification规格/型号	CTN/NO;箱数	Quantity数量
EZ Cartridge	18-08			10CTNS

生产确认	
加药者:	汪瑶
操作者:	汪瑶
灭菌主管:	宋江
质检员:	
品管部主管:	
验收	<input checked="" type="checkbox"/> 合格 <input type="checkbox"/> 不合格 <input type="checkbox"/> 待定

Process Parameters过程参数	Setting Value 设定值	Actual Value 实际值		Requirement要求		Pass/Fail 合格/不合格
				min最小值	max最大值	
Vaccum value (KPa)预真空度	-50.0	-50.2		-52.0	-48.0	Pass
Leak test time(min)泄漏测试时间	5	5		4	6	Pass
Pressure change at end of leak test (KPa)泄漏压力值	---	0.2		0.0	3.0	Pass
Pressure change at end of steam injection (KPa)加湿后压力变化值	2.0	19.6	前:-50.0后:-30.4	1.0	3.0	Fail
Pressure change at end of EO injection (KPa)加EO后压力变化值	99.0	36.9	前:-30.4后:6.5	0.0	100.0	Pass
EO weight injected(Kg)加EO量	---			0.0	10.0	Pass
Temperature (T1) during EO exposure(℃)灭菌阶段柜体温度	50.0	Min: 49.3	Max: 52.0	45.0	55.0	Pass
Humidity (RH) during EO exposure(% RH)灭菌阶段柜体湿度	---	Min: 38.1	Max: 51.6	30.0	85.0	Pass
Pressure (P1) during EO exposure (Kpa) 灭菌阶段柜体压力	---	Min: 0.3	Max: 6.5	---	---	Pass
EO dwell (min)灭菌时间	480	480		479	481	Pass
Numbers of air washes空气冲洗次数	3	3		2	4	Pass

Sterilization Process 灭菌过程	Start time 开始时间	End time 结束时间	Time elapsed(min) 耗时
Heating加热	2018/8/11 19:43	2018/8/11 20:54	71
Keeping warm保温	2018/8/11 20:54	2018/8/11 21:54	60
Pre-vacuum初始真空	2018/8/11 21:54	2018/8/11 22:01	7
leak test泄漏检测	2018/8/11 22:01	2018/8/11 22:06	5
steam injection加湿	2018/8/11 22:06	2018/8/11 22:27	21
EO injection加药	2018/8/11 22:27	2018/8/11 23:10	43
EO dwell灭菌	2018/8/11 23:10	2018/8/12 7:10	480
EO Removal EO移除	2018/8/12 7:10	2018/8/12 7:16	6
air washing 空气清洗	2018/8/12 7:16	2018/8/12 7:35	19
repressure 放空	2018/8/12 7:35	2018/8/12 8:08	33

下列产品:

发证时间: 2018-07-18  
履行地点: 江阴市

**ACCS**  
REGISTRARS  
CERTIFICATE



This is to certify that

**Suzhou Dezhen Metal Products Co. Ltd.**

**Registered address:** Huwan Village, Huangqiao Street, Xiangcheng District, Suzhou City, Jiangsu Province, China

**Manufacturing site:** Huwan Village, Huangqiao Street, Xiangcheng District, Suzhou City, Jiangsu Province, China

Quality Management System has been audited and found to comply with the following requirements

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

For the following activities

Metal products, stainless steel wire and stainless steel products  
production, processing and sales

Certificate No.: KB-2017Q1408

Initial date issued: 2017-08-10

Current certificate valid until: 2018-08-09

Valid until: 2020-08-09

Ver. 02

*This certificate in the state regulations administrative licence, Qualification, Mandatory product certification received within the validity period and the normal annual review of the case effectively.  
To verify that this certificate is current please refer to CNCA website at <http://www.cnca.gov.cn>*



签署:

凯邦检测认证(上海)有限公司-ACCS Certification (Shanghai) Co., Ltd.

中国-上海市虹口区天宝路578号凯康世纪大厦9楼914室; 电话: 021-55828339; 传真: 021-65108839  
网址: <http://www.acsiso9000.com>; 邮箱: [acschina@cnzdkb.org](mailto:acschina@cnzdkb.org)