



Asia Dynamics Inc.

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CERTIFICATE OF COMPLIANCE AND STERILITY

Issue Date: 2024-03-28

This is certifying that the products listed below are in compliance with ISO13485:2016 standard and current FDA Quality System Requirements (QSR) as stipulated in 21 CFR Part 820.

PO#	Item#	Description	Pcs/Cs	Q'ty/Cs	Lot#	Sterilization Lot #	Exp Date
YD-4490	EA-REF50122-50	Sterile PVP Solution 10% PVP Solution 3/4Oz	300	1	20240325	S1-20240320-5719N2	2027-01-28

Conclusion:

A review of the applicable Device History Record(s) has been conducted and the device was manufactured in accordance with the requirements specified in the Device Master Record.

A review of primary identification labels and labeling used for production units was conducted and confirmed to be correct.

This shipment is in conformance with the Specification listed and meets all requirements necessary for product release.

Product samples representative of this lot of production is guaranteed to be sterilized.

The sterilization by ETO gas is per international standards ISO11135:2014.

The sterilization by Gamma Radiation is per international standards EN ISO11137-1

Name and Title of Responsible Offer

Jerry Zhu

客户名称 Customer:	ADI Medical		
灭菌日期 Sterilization Date	2024年03月20日	灭菌批号 Sterilization Lot	S1-20240320-5719N2
Product Name 产品名称	Product Item# 产品代码	LOT# 产品批号	Quantity (Carton) 产品数量(箱)
消毒液	EA-REF50122-50	20240325	6

Changshu Rozer Sterilization Technology Co.,Ltd. hereby certifies that products listed above have been sterilized by ETO gas per sterilization process #APD-14-16, the sterilization process has been validated in accordance with AAMI/ISO11135:2014 at Sterility Assurance Level 10⁻⁶.
常熟荣瑞灭菌技术有限公司在此证明以上列出的产品已经按照灭菌工艺APD-14-16进行环氧乙烷气体灭菌，该灭菌工艺事先已经按照10⁻⁶无菌保障水平和专业标准AAMI/ISO11135:2014完成验证。

The main parameters were listed as follows 主要工艺参数列出如下:
1) The pressure after ETO gas injected is 40 to 43 Kpa. 加入环氧乙烷 (ETO) 后的压力为40-43Kpa.
2) The temperature is maintained at 45-53 degrees centigrade. 温度维持在45-53℃.
3) The exposure duration:320-330 Min. 曝气灭菌时间: 320-330分钟.
4) The sterilization equipment is certified, licensed, and validated. 灭菌设备是被资质证明和验证的.
5) All records are maintained on file. 所有记录已进行保存.

签发人Certified by: 沈依

日期Date: 2024.3.25



荣瑞灭菌
ROZER

灭菌过程参数核对表
Sterilization Parameters Checklist

工艺号 Cycle No.	Cycle#06	灭菌批号 Load No.	S1-20240320-5719N2	
产品信息 Products Information				
Precondition process 预热	预热房号	PCR-2	区位号	C
预热开始日期/时间	2024/3/20 8:50		预热结束日期/时间	2024/3/20 20:00
Precondition Parameter 预热参数	Set Point 设定值	Measure Tolerance 测量允许范围		Actual Measurement 实际测量值
		Min 最小值	Max 最大值	
Temperature 温度 °C	48°C	43°C	55°C	43.8 49.3
Humidity 湿度 %	55%	30%	80%	50.9 58.7
Time 时间 min	N/A	660min	2880min	670
预热-灭菌 运送时间 min	N/A	≤60		18
Sterilization 灭菌	柜号: S1			
灭菌开始日期/时间	2024/3/20 20:18		灭菌柜开门日期/时间	2024/3/21 6:37
Parameter 参数	Set Point 设定值	Measure Tolerance 测量允许范围		Actual Measurement 实际测量值
		Min 最小值	Max 最大值	
加热及保温参数				
保温温度	48°C	45°C	53°C	48.0 48.8
保温时间	5min	3min	7min	5
真空及检漏				
Initial Evacuation 初始真空度	-60kpa	-61kpa	-59kpa	-60.0
检漏压力变化量	N/A	0kpa	2kpa	0.1
检漏所需时间	8min	6min	10min	8
氮气置换				
氮气置换次数 (times)	2	2	2	2
加氮气停止压力	-10kpa	-11kpa	-9kpa	-9.9 -9.9
抽真空压力	-60kpa	-61kpa	-59kpa	-60.1 -60.0
加湿参数				
加湿压力差	1kpa	0.5kpa	1.5kpa	1.0
保湿时间	5min	4min	6min	5
加药参数				
最低允许的进药温度	N/A	15°C	60°C	23.0 48.4
加药压力变化	41kpa	40.0kpa	43.0kpa	41.0
加药时间	N/A	28min	82min	46
投放EO重量	N/A	40kg	85kg	58.8
TANK NO 钢瓶号	1284		批号	WE10F42172
投药结束补气参数				
氮气注入变化压力	10kpa	9kpa	11kpa	10.0
加氮气时间	N/A	2min	10min	3
灭菌阶段参数				
灭菌温度	48°C	45°C	53°C	46.2 49.2
灭菌湿度	N/A	0%	99%	42.6 51.0
灭菌时间 (min)	325	320	330	325
EO 理论浓度 (mg/L)	N/A	649	716	676.8
柜内气体循环系统状态	On	On / Off		On
氮气清洗及空气清洗参数				
氮气置换次数 (times)	2	2	2	2
抽真空压力	-60kpa	-61kpa	-59kpa	-60.0 -60.1
加氮气停止压力	-10kpa	-11kpa	-9kpa	-9.9 -9.9
空气清洗次数	1	1	1	1
抽真空压力	-60kpa	-61kpa	-59kpa	-60.0
加空气停止压力	-10kpa	-11kpa	-9kpa	-10.0
除残参数				
除残时间	3min	2min	20min	13
除残压力变化范围	N/A	-20kpa	3kpa	-16.8 -2.5
解析				
解析开始日期/时间	2024/3/21 6:59		解析结束日期/时间	2024/3/22 6:22
Parameter 参数	Set Point 设定值	Measure Tolerance 测量允许范围		Actual Measurement 实际测量值
		Min 最小值	Max 最大值	
灭菌-解析 运送时间 (min)	N/A	≤60		22
温度	42°C	37°C	50°C	38.4 44.4
时间	N/A	1110min-4320min		1403
BI培养				
菌片生产商	Mesa	菌片批号		G-239
培养箱编号	N/A	N/A	N/A	21081124
Number of BIs 生物指示剂数量	30+1	30+1	30+1	30+1
自含式BI培养的温度	37°C	35°C	39°C	37°C
培养开始时间	2024/3/21 12:46		培养结束时间	2024/3/25 12:51
Observed Item 观察结果				-
Positive Control 阳性对照				+
<input checked="" type="checkbox"/> Accept 接受 <input type="checkbox"/> Non Conformance 不符合				
DESCRIPTION OF NONCONFORMITY 不符合描述				
N/A				
Non-Conforming Report No. 不符合报告编号:	N/A	IDENTIFIED BY (SIGN, DATE) 签名, 日期		N/A
Note 备注: N/A				

Reviewed by 审核 /Date 日期: *[Signature]* 2024.3.25

Checked by 核对者 /Date 日期: *[Signature]* 2024.3.25