Medical Device Manufacturing Co;Ltd

医疗器械有限公司

| **VALIDATION REPORT 验证报告** | |
|---|---|
| Silicone Drainage Product Family Fractional Cycle Qualification Report in current Sterilization Chamber<br>硅胶引流产品族在现有灭菌柜的短周期确认报告 | |
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## 目录 Content

## 1. 验证目标 Validation Objective

1.1.此次短周期确认的目的是证实及用文件记录在现有的灭菌柜内，通过采用的预先设定的短周期灭菌循环参数，确定适合的过程挑战装置，用于接下来的硅胶引流产品族性能确认(PQ)。同时通过短周期循环证明实验室复苏存活的微生物技术及确认 EO 抗性 EPCD≥IPCD≥产品初始生物负载。

The purpose of this fractional cycle qualification is to demonstrate and document the appropriate PCD through predefined fractional cycle parameters for the upcoming Silicone Drainage Product Family Performance Qualification (PQ), also to demonstrate that survivors can be recovered in the laboratory and the EO resistance hierarchy EPCD ≥ IPCD ≥ Natural product bioburden.

## 2. 报告总结 Report Conclusions

2.1.证实 Have demonstrated that：

2.1.1. 短周期循环结果 Fractional cycle results：

2.1.1.1. IPCD 与 EPCD 的 EO 抗性结果如下 The EO resistance of two IPCDs and EPCD is as listed:

| Cycle 循环 | IPCD1 Results (No. of Positives / Total No. of BI Tested ) 内置挑战装置 1 BI 阳性/总数 | IPCD2 Results (No. of Positives / Total No. of BI Tested ) 内置挑战装置 2 BI 阳性/总数 | EPCD Results (No. of Positives / Total No. of BI Tested ) 外置挑战装置 BI 阳性/总数 |
|---|---|---|---|
| Fractional Cycle 短周期 | 0/18 | 3/18 | 6/18 |

2.1.1.2. 产品无菌检测结果如下 The products sterility test results are as listed:

| Cycle 循环 | Product 产品 | Product Lot 产品批号 | Media/Temp. 培养基/温度 | Results (No. of Positives/ Total No. of Samples Tested) 测试结果阳性/总数 |
|---|---|---|---|---|
| Fractional cycle 短周期循环 | 硅胶圆形开槽管 10Fr 带引导针（粘接） JP CHAN DRN SIL RND 10FR FULL W/TRO | 200458 | TSB/20-25℃ | 0/20 |
| | | | FTM/30-35℃ | 0/20 |
| | 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接） JP CHAN DRN SIL RND 15FR 3/4 W/TRO | 200458 | TSB/20-25℃ | 0/20 |
| | | | FTM/30-35℃ | 0/20 |

结论 Conclusion

a. 通过短周期循环，产品无微生物生长，部分来自 IPCDs 和 EPCDs 的 BI 经过培养生长阳性。

Through fractional cycle results, the products showed no growth , partial BIs from IPCDs and EPCDs showed growth .

b. 通过短周期循环，确认了合适的 PCD，为产品 - 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接）,以此产品制备 IPCD，用于产品族半周期循环确认。

Through fractional cycle results,the appropriate PCD was confirmed, that is product JP CHAN DRN SIL RND 15FR 3/4 W/TRO-IPCD2.And use this product to build the IPCD for the product family half cycles qualification.

c. 通过短周期循环, EO 抗性 EPCD ≥ IPCD ≥ 产品初始生物负载得到证实。

Through fractional cycle results,the EO resistance hierarchy EPCD ≥ IPCD ≥ natural product bioburden have been demonstrated.

d. 阳性测试样品显示阳性，从而证实实验室足够的复苏技术。

Positive control test articles showed growth, thereby demonstrating the adequacy of the recovery technique of the lab.

e. 阴性测试样品无微生物生长。

Negative control test articles showed negative for growth.

f. 方案附录 1 的参数必须满足。

Process Parameters as per Appendix 1 for fractional cycle protocol has been met.

g. 产品的平均初始生物负荷不能超过 100CFU/套，符合接受标准，结果如下：

The average bioburden of the product did not exceed 100 CFU/device, complying with the acceptance criteria, the details results are as listed:

| 产品 Product | 批号 Lot No. | 平均初始生物负荷（菌落数/套）Average Bioburden Level (CFU/Device) |
|---|---|---|
| 硅胶圆形开槽管 10Fr 带引导针（粘接）<br>JP CHAN DRN SIL RND 10FR FULL W/TRO | 200458 | 80 |
| 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接）<br>JP CHAN DRN SIL RND 15FR 3/4 W/TRO | 200458 | 85 |

2.2.在现有灭菌柜用于此次短周期确认的产品装载为模拟最具挑战性的非销售工程样品，适用于以下产品:

The fractional cycle qualification was conducted in existing EO sterilization chamber with non-saleable engineering products to built for dunnage load simulating the most challenging routine load, and applicable for the products given below:

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| 序号<br>No. | 代码<br>Code | 产品描述<br>description | 产品名称<br>Name | 外箱尺寸<br>dimension(cm) | 每箱数量<br>Quantity per box(pcs) | 包装重量/箱<br>Weight/box (kg) | 灭菌箱数/层数<br>Boxes/layers | 产品体积<br>Volume($m^3$) | 密度 density<br>($kg/m^3$) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | JP-2186 | 硅胶圆形开槽管 10Fr 不带引导针（粘接）JP CHANNEL DRAIN 10FR, FULL FLUTES | Silicone round drain, full channels without trocar | 47*36*25 | 80 | 1.3 | 60/3 | 0.042 | 30.952 |
| 2 | JP-2187 | 硅胶圆形开槽管 10Fr 带引导针（粘接）JP CHAN DRN SIL RND 10FR FULL W/TRO | Silicone round drain, full channels with trocar | 47*36*25 | 80 | 2.0 | 60/3 | 0.042 | 47.619 |
| 3 | JP-2188 | 硅胶圆形开槽管 15Fr 不带引导针（粘接）JP CHANNEL DRAIN 15FR, FULL FLUTES | Silicone round drain, full channels without trocar | 47*29*47 | 80 | 1.8 | 60/3 | 0.064 | 28.125 |
| 4 | JP-2189 | 硅胶圆形开槽管 15Fr 带引导针（粘接）JP CHAN DRN SIL RND 15FR FULL W/TRO | Silicone round drain, full channels with trocar | 47*29*47 | 80 | 3.8 | 60/3 | 0.064 | 59.375 |
| 5 | JP-2190 | 硅胶圆形开槽管 19Fr 不带引导针（粘接）JP CHANNEL DRAIN 19FR, FULL FLUTES | Silicone round drain, full channels without trocar | 47*29*47 | 80 | 2.1 | 60/3 | 0.064 | 32.813 |
| 6 | JP-2191 | 硅胶圆形开槽管 19Fr 带引导针（粘接）JP CHAN DRN SIL RND 19FR FULL W/TRO | Silicone round drain, full channels with trocar | 47*29*47 | 80 | 4.1 | 60/3 | 0.064 | 64.063 |
| 7 | JP-2210 | 硅胶扁平开槽管 7mm 不带引导针 3/4JP CHANNEL DRAIN 7MM, 3/4 FLUTES | Silicone flat drain without trocar | 47*36*25 | 80 | 2.1 | 60/3 | 0.042 | 50.000 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8 | JP-2211 | 硅胶扁平开槽管 7mm 不带引导针 全开槽 JP CHANNEL DRAIN 7MM, FULL FLUTES | Silicone flat drain without trocar | 47*36*25 | 80 | 1.7 | 60/3 | 0.042 | 40.476 |
| 9 | JP-2212 | 硅胶扁平开槽管 7mm 带引导针 全开槽 JP CHAN DRN SIL FLT 7MM FULL W/TRO | Silicone flat drain with trocar | 47*36*25 | 80 | 3.7 | 60/3 | 0.042 | 88.095 |
| 10 | JP-2213 | 硅胶扁平开槽管 10mm 不带引导针 3/4JP CHANNEL DRAIN 10MM, 3/4 FLUTES | Silicone flat drain without trocar | 47*36*25 | 80 | 2.3 | 60/3 | 0.042 | 54.762 |
| 11 | JP-2214 | 硅胶扁平开槽管 10mm 不带引导针 全开槽 JP CHANNEL DRAIN 10MM, FULL FLUTES | Silicone flat drain without trocar | 47*36*25 | 80 | 2.1 | 60/3 | 0.042 | 50.000 |
| 12 | JP-2215 | 硅胶扁平开槽管 10mm 带引导针 全开槽 JP CHAN DRN SIL FLT 10MM FULL W/TRO | Silicone flat drain with trocar | 47*36*25 | 80 | 3.8 | 60/3 | 0.042 | 90.476 |
| 13 | JP-2216 | 硅胶扁平开槽管 7mm 带引导针 3/4 JP CHAN DRN SIL FLT 7MM 3/4 W/TRO | Silicone flat drain with trocar | 47*36*25 | 80 | 3.9 | 60/3 | 0.042 | 92.857 |
| 14 | JP-2217 | 硅胶扁平开槽管 10mm 带引导针 3/4 JP CHAN DRN SIL FLT 10MM 3/4 W/TRO | Silicone flat drain with trocar | 47*36*25 | 80 | 4.0 | 60/3 | 0.042 | 95.238 |
| 15 | JP-2221 | 硅胶圆形开槽管 10Fr 带引导针 3/4 （粘接） JP CHAN DRN SIL RND 10FR 3/4 W/TRO | Silicone round drain, 3/4 channels with trocar | 47*36*25 | 80 | 2.1 | 60/3 | 0.042 | 50.000 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 16 | JP-2223 | 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接）JP CHAN DRN SIL RND 15FR 3/4 W/TRO | Silicone round drain, 3/4 channels with trocar | 47*29*47 | 80 | 4.0 | 60/3 | 0.064 | 62.500 |
| 17 | JP-2225 | 硅胶圆形开槽管 19Fr 带引导针 3/4（粘接）JP CHAN DRN SIL RND 19FR 3/4 W/TRO | Silicone round drain, 3/4 channels with trocar | 47*29*47 | 80 | 4.1 | 60/3 | 0.064 | 64.063 |
| 18 | JP-2226 | 硅胶圆形开槽管 10Fr 不带引导针 JP CHANNEL DRAIN 10FR HUBLESS | Hubless silicone round drain without trocar | 47*36*25 | 80 | 1.2 | 60/3 | 0.042 | 28.571 |
| 19 | JP-2227 | 硅胶圆形开槽管 10Fr 带引导针 JP CHANNEL DRAIN 10FR HUBLESS | Hubless silicone round drain with trocar | 47*36*25 | 80 | 2.0 | 60/3 | 0.042 | 47.619 |
| 20 | JP-2228 | 硅胶圆形开槽管 15Fr 不带引导针 JP CHANNEL DRAIN 15FR HUBLESS | Hubless silicone round drain without trocar | 47*29*47 | 80 | 2.1 | 60/3 | 0.064 | 32.813 |
| 21 | JP-2229 | 硅胶圆形开槽管 15Fr 带引导针 JP CHAN DRN SIL HUBLESS 15FR W/TRO | Hubless silicone round drain with trocar | 47*29*47 | 80 | 3.9 | 60/3 | 0.064 | 60.938 |
| 22 | JP-2230 | 硅胶圆形开槽管 19Fr 不带引导针 JP CHANNEL DRAIN, 19FR HUBLESS | Hubless silicone round drain without trocar | 47*29*47 | 80 | 3.0 | 60/3 | 0.064 | 46.875 |
| 23 | JP-2231 | 硅胶圆形开槽管 19Fr 带引导针 JP CHAN DRN SIL HUBLESS 19FR W/TRO | Hubless silicone round drain with trocar | 47*29*47 | 80 | 5.8 | 60/3 | 0.064 | 90.625 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 24 | JP-2232 | 硅胶圆形开槽管 19Fr 带可弯曲引导针 JP CHAN DRN SIL HUBLES 19FR BND TRO | Hubless silicone round drain with bendable trocar | 47*29*47 | 80 | 5.6 | 60/3 | 0.064 | 87.500 |
| 25 | JP-2233 | 硅胶圆形开槽管 15Fr 带可弯曲引导针 JP CHAN DRN SIL HUBLES 15FR BND TRO | Hubless silicone round drain with bendable trocar | 47*29*47 | 80 | 3.7 | 60/3 | 0.064 | 57.813 |
| 26 | JP-2234 | 硅胶圆形开槽管 24Fr 带引导针 JP CHANNEL DRAIN, 24FR HUBLESS | Hubless silicone round drain with trocar, 43" total length | 47*29*47 | 80 | 9.1 | 60/3 | 0.064 | 142.188 |
| 27 | JP-2290 | 硅胶圆形开槽管 28Fr 不带引导针 CHANNEL DRAIN, 28FR, HUBLESS | Hubless silicone round drain without trocar, 43" total length | 47*29*47 | 80 | 5.07 | 60/3 | 0.064 | 79.219 |
| 28 | JP-2292 | 硅胶圆形开槽管 32Fr 不带引导针 CHANNEL DRAIN, 32FR, HUBLESS | Hubless silicone round drain without trocar, 43" total length | 47*29*47 | 80 | 6.57 | 60/3 | 0.064 | 102.656 |

## 3. 实施概述 Execution Summary

3.1. 前提步骤 Prerequisite Steps

3.1.1. 在短周期确认活动实施前，确认现有灭菌柜的安装确认及运行确认报告，相关报告已存档。

Verification of the IQ and OQ documentation of existing chamber had been done prior to the fractional cycle qualification, and the documents were archived.

3.1.2. 相关人员的培训已实施，培训记录见附录 1。

Training on the fractional cycle qualification was conducted for all involved personnel and the training record see attachment 1.

3.1.3. 核实温湿度无线探头，安装于灭菌柜上的温度压力传感器及其他辅助设施的计量仪表的校验记录是否符合接受要求，计量仪表校验状态见仪表校验清单，符合接受要求。仪表校验状态记录见附录 2。

All calibration records/ results of the temperature/ relative humidity data loggers, the temperature,RH sensors & pressure transmitter fitted to the sterilization chamber and other measurement instruments associated with the ancillary equipment were reviewed for acceptance. The calibration status for each equipment was identified in the equipment calibration list and was found to be acceptable. The record of equipment calibration status is presented in attachment 2.

3.1.4. 核实了设备维护的状态。所有的设备均依照灭菌设备维护程序规定的时间表进行维护，并用文件记录维护活动， 维护记录存档。

The status of equipment maintenance was also reviewed. All identified equipment was conducted according to the time schedule. The maintenance activities were documented and the records were archived in files.

3.2. 装载 Load

3.2.1. 完整的非销售产品(满载）用于此次性能验证，产品装载体积 4.1 $m^3$。

The complete load of non-saleable products (full load) had been used for the fractional cycle qualification . The product load volume as derived in protocol is 4.1 $m^3$.

3.2.2. 灭菌柜内产品的装载，内置挑战装置，外置挑战装置，无菌测试产品样品，无线温湿

度探头的放置参考验证方案附录 2。

The load configuration in the chamber, and the placement of IPCDs, EPCDs, product test samples and data loggers (temperature and humidity sensors) in the load were placed according to attachment 2 of the protocol.

3.3.过程挑战装置 PCDs

3.3.1. 用于此次短周期确认的内置挑战装置采用产品 1 -硅胶圆形开槽管 10Fr 带引导针（粘接），产品 2 - 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接）。

Two units of IPCD were used in this fractional cycle qualification, the products adopted were: Product 1 - JP CHAN DRN SIL RND 10FR FULL W/TRO-IPCD1, Product 2 - JP CHAN DRN SIL RND 15FR 3/4 W/TRO-IPCD2.

3.3.2. 用于短周期循环确认的内置挑战装置，其制备参考验证方案要求进行。

The IPCDs used in this fractional cycle qualification. They were prepared according to the requirements of the protocol.

3.3.3. 内置挑战装置植入枯草芽孢杆菌，平均菌落数为≥1.0 × $10^6$/条，D 值在 54°C ≥2.5 分钟，符合验证方案的要求。

The IPCDs were inoculated with biological indicator (Bacillus atrophaeus). The average spore concentration was ≥1.0 × $10^6$/strip and the D value of the BI was ≥2.5 minutes at 54°C which met the acceptance criteria as defined in the of the protocol.

3.4.此次验证半周期所用的内置挑战装置数量为 18 个（2 种）,外置挑战装置 18 个。

A total of 18 units of IPCD (two IPCDs) and 18 units of EPCD for fractional cycle qualification were used .

3.5.无菌检测样品 Product sterility samples

3.5.1. 依照验证方案的要求，40 个产品（两种），这些样品依照验证方案附录 2 的要求放置在产品装载中进行,用于产品无菌检测。

40 units of product (two products) were prepared for product sterility test, according to the protocol requirements. They were placed in the load according to appendix 2 of the protocol and processed in the fractional cycles.

3.5.2. 2 个产品（2 种）的初始生物负荷实施了测试，测试结果在接受标准内。

2 units of product（2 products）bioburden test in this fractional cycle was conducted, and the testing results met the acceptance criterion.

3.6. 无线探头 Data Loggers

3.6.1. 校验完的温湿度无线探头用于短周期循环。

Calibrated temperature and humidity data loggers were used in the fractional cycle qualification

3.6.2. 总计 6 个温度，3 个湿度探头依照验证方案附录 2 的要求放置在装载指定的位置。

A total of 6 T and 3 RH data loggers were placed in the locations stipulated in appendix 2 of the protocol.

3.7. 结果 Results

3.7.1. 过程参数 Process Parameters

3.7.2. 短周期循环符合规定的过程参数（温度，EO 用量均采用设定值下限），完成的循环参数报告和灭菌循环记录包括设定值及范围见本报告附录 3。

The fractional cycle met the predefined cycle parameters(the sterilization temperature and EO usage all adopted the setting low limit. The filled cycle parameter sheets (appendix 1 of the protocol) and the cycle run records including set points and tolerance are enclosed within this completion report in attachment 3.

3.8. 装载的物理性质 Physical profiles of loads

3.8.1. 装载的温湿度分布见附录 4

The temperature and humidity profiles are presented in attachment 4.

3.8.2. 装载的温湿度分布在短周期循环及全周期循环不同阶段的表现见如下列表：

A summary of the load response at different phases of the fractional cycle run s tabulated below:

表 1Table 1: 装载温度 Load Temperature Data

| PHASES 阶段 | Load Parameter 装载参数 | Fractional Cycle 短周期 | Position 位置 |
|---|---|---|---|
| Start of the cycle 循环开始 | Min. Load Temp.最低装载温度 | 24.6℃ | T3 |
| Preconditioning 预热 | Min. Load Temp.最低装载温度 | 24.6℃ | T3 |
| | Max. Load Temp.最高装载温度 | 36.8℃ | T5/T6 |
| | Min. Load Humidity 最低湿度 | 72.8% | H3 |
| | Max. Load Humidity 最高湿度 | 82.9% | H1 |
| | Min. Load Temp. at the end of Preconditioning Phase 预热结束后的最低温度 | 31.4℃ | T2 |
| | Max. Load Temp. at the end of Preconditioning Phase 预热结束后的最高温度 | 36.8℃ | T5/T6 |
| | Min. Load Humidity at the end of Preconditioning Phase 预热结束最低湿度 | 72.8% | H3 |
| | Max. Load Humidity at the end of Preconditioning phase 预热结束最高湿度 | 82.9% | H1 |
| EO Exposure time 灭菌暴露阶段 | Min. Load Temp.最低装载温度 | 31.8℃ | T2 |
| | Max. Load Temp.最高装载温度 | 41.6℃ | T5 |
| | Average load Temp.平均装载温度 | 36.9℃ | N/A |
| | Min. Load Humidity 最低装载湿度 | 65.8% | H3 |
| | Max. Load Humidity 最高装载湿度 | 86.6% | H1 |
| Aeration 解析 | Min. Temp.最低温度 | 36.2℃ | T2 |
| | Max. Temp.最高温度 | 42.1℃ | T5 |

备注 Note: N/A-不存在

3.8.3. 加药及清洗阶段的压力变化 Pressure rise during gas injection and washing phase

Table- 2 压力变化数据 Pressure rise profile

| Phase 阶段 | Fractional Cycle<br>短周期 |
|---|---|
| EO pressure change (kpa)<br>加药后的压力变化 | 31.8 |
| EO charge (min)<br>加药时间 | 4 |
| Rate(kpa/min)速率 | 8.0 |
| Final pressure (kpa)<br>最终压力 | -35.1 |
| Mass of EO used (kg)<br>使用的 EO 量 | 4 |
| EO concentration (mg/L)<br>EO 浓度 | 519.9 |

**6.5 Method of determining EO gas concentration based on physical laws of perfect gas behavior**

**6.5.1 100 % EO sterilant**

When the sterilant gas injected into the sterilizer chamber is 100 % EO, the mean EO gas density (concentration) within the chamber may be determined by using the relationship shown in Equation (5) and as shown in Example 1 as follows:

$$C_{eo} = \frac{M_{eo(g/mole)} P_{eo(atm)}}{R_{(liter-atm/Kelvin-mole)} T_{(Kelvin)}}, \qquad \text{(equation 5)}$$

where

$M_{eo}$ = 44.054 g/mole (molecular weight of EO)
$C_{eo}$ = mean EO gas concentration in mg/L
$P_{eo}$ = partial pressure of EO gas injected into the chamber

3.8.4. 初始生物负荷测试 Product Bioburden Testing

3.8.4.1. 依照要求对未灭菌样品进行产品（2 种）初始生物负荷进行测试。

The product bioburden testing was performed on non-sterile samples (two products), and the results comply with the acceptance criteria.

3.8.5. 实施了生物指示剂培养（来自内置挑战装置,外置挑战装置），EO 抗性得到了确认。

The biological indicators incubation (from IPCDs and EPCDs) was conducted and the EO resistance of EPCD and IPCD is confirmed.

3.8.5.1. 培养结果显示部分 IPCD 显示阳性，部分 EPCD 显示阳性，且 EPCD 阳性数多于 IPCD 阳性数。

The incubation results showed partial IPCDs showed growth,partial EPCDs showed growth, and the positive BI quantity is higher than IPCDs.

3.8.5.2. 阳性对照显示生长，阴性对照显示不生长。

All positives controls showed growth and all negative controls showed no growth.

3.8.6. 产品无菌测试 Product Sterility Testing

3.8.6.1. 对产品样品进行了无菌检测。

Testing of product samples was performed .

3.8.6.2. 经历周期循环的 40 个产品（2 种产品）无菌检测均不显示生长，阳性控制显示生长，阴性显示不生长。

Total 40 units product sterility test samples (two products) processed in the fractional cycle run were tested and all exhibited negative growth. The positive controls showed growth and negative controls showed no growth.

3.8.7. 对来自 IPCDs 和 EPCDs 的 BI 进行了培养，培养结果确认了合适的 PCD 和 EO 抗性，符合接受标准。

3.8.8. 产品处置 Disposition of the products

此次短周期确认所采用的产品装载为非销售产品，故无需对产品进行处置。

The loads used for this fractional cycle qualification are made of non-saleable products, thereby no products disposal requirements.

**4. 纠正措施 Corrective Actions:**

在实施性能验证过程中未发现偏差，故无需纠正措施。

There is no deviation reported during execution of this performance qualification, hence corrective action is not required.

**5. 可交付性 Deliverables:**

基于短周期的确认结果，产品硅胶圆形开槽管 15Fr 带引导针 3/4（粘接），可用于制备 IPCD，用于产品族的半周期循环确认。

Based on the fractional cycle qualification, product - JP CHAN DRN SIL RND 15FR 3/4 W/TRO will be used to build the IPCD for product family half cycles qualification.

**6. 附录 Appendices**

Attachment 1 – 相关人员的培训记录 Training record of relevant staff

Attachment 2 – 仪表校验清单及验证记录 Instruments Calibration review check list and calibration records.

Attachment 3 - 灭菌循环记录（灭菌报告）Run records (cycle reports)

Attachment 4 – 温湿度分布数据 Temperature & humidity data and profiles.

Attachment 5 – 微生物确认测试报告（生物指示剂，产品无菌检测报告，产品初始生物负荷报告）

Microbiological Qualification Test Reports (BI & product sterility test,bioburden test).

Attachment 6 – EO 气体及生物指示剂符合性证书 Certificates of compliance of EO gas and Biological indicator.