Device Manufacturing Co;Ltd

医疗器械有限公司

VALIDATION PROTOCOL 验证方案	
Silicone Drainage Product Family Half Cycles Qualification Protocol in current Sterilizer 硅胶引流产品族在现有灭菌柜的半周期确认方案	
File Number 文件编号	

Revision History 修订历史		
Version 版本号	Description 描述	Written By/起草者 Date/日期
01	1st Version	

Validation Team 验证团队	Name/Position 姓名/职位	Signature 签名	Date 日期
Written By 起草者	Xu Sijia/Validation Supervisor 徐思佳/验证主管		
Reviewer 审核者	Xu Sijia/Quality Manager 徐思佳/品质部经理		
Reviewer 审核者	Ji Wenlong/TS Manager 吉文龙/技术部经理		
Reviewer 审核者	Chen Guangxu/Production Manager 陈光圩/生产部经理		
Approver 批准者	Zhang Yehua/GM 张叶华/总经理		

Device Manufacturing Co;Ltd

医疗器械有限公司

目录

1. 验证目标 Validation Objective

1.1.此次半周期确认的目的是证实及用文件记录在现有的灭菌柜内采用的预先设定的灭菌循环，通过实施灭菌微生物杀灭（MPQ）及物理性研究（PPQ）能够实现现有产品族的无菌保证水平 10^{-6}。此方案的设计持续符合 ISO 11135:2014-医疗产品灭菌-环氧乙烷-医疗器械灭菌过程的发展，验证及常规控制的要求。

The purpose of this Half Cycles Qualification is to demonstrate and document the attainment of a minimum Sterility Assurance Level of 10^{-6} for the sterilization of exiting product family in existing EO Sterilization Chamber through the execution of sterilization microbiological lethality studies (MPQ) and physical studies (PPQ) using predetermined sterilization cycle.This protocol is designed to be consistent with ISO 11135:2014 Sterilization of health care products - Ethylene oxide-Requirements for development, validation and routine control of a sterilization process for medical devices.

2. 范围 Scope

2.1.设备描述 Equipment Description

2.1.1. EO 灭菌柜 EO sterilization Chamber，型号 type： HDX-6/，编码 code：U12-6-30/CE ，供应商 supplier：杭州优尼克消毒设备有限公司 Hangzhou Unique disinfection equipment Co;Ltd.

2.1.2. 灭菌柜内部尺寸 EO sterilizer inner dimension：L - 2800mm, W - 1350mm, H - 1700mm, 总体积 Total volume 6m^3.

2.2.循环定义 Cycle Definition

2.2.1. 将依照附录 1 所指定的参数运行三个连续的半周期。

Three half cycles will be conducted as per the parameters as given in appendix 1

2.3.产品定义 Product Definition

2.3.1. 此方案适用于下列产品。

This protocol applies to the listed products including loading configuration

Device Manufacturing Co;Ltd

医疗器械有限公司

序号 No.	代码 Code	产品描述 description	产品名称 Name	外箱尺寸 dimension(cm)	每箱数量 Quantity per box(pcs)	包装重量/箱 Weight/box (kg)	灭菌箱数/层数 Boxes/layers	产品体积 Volume(m^3)	密度 density (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

2.4.产品装载 Load Configuration

2.4.1. 一个完整的验证装载包含 60 箱模拟产品,与产品常规装载相同,采用与产品 24Fr 硅胶引流管相似的材料制备而成，采用相同的无菌屏障系统和中包装，代表常规生产中最具挑战的产品装载，密度≥142.188kg/m^3，产品装载体积 4.1m^3。

A full validation load shall consist of 60 boxes of non-saleable dunnage products, same as routine production load configuration, using 24Fr Silicone Drainage Product similar construction materials to build,same SBS and same second package, representing the most challenging routine load, the density ≥142.188 kg/m3，product load volume 4.1m^3.

3. 职责 Responsibilities

部门 Department	验证工作组职位 Validation Group Position	姓名 Name	职责 Responsibilities
Validation Supervisor 验证主管	验证工作小组成员 Member of Validation Team	Xu Sijia 徐思佳	起草验证方案，并对此次方案的信息内容由设备的功能的输入进行整合，并反映在此文件中。 Write the Validation Protocol. The information in this protocol was assembled from the input of the other functions in this facility and is accurately reflected within this document
Quality Manager 品质部经理	验证工作小组成员 Member of Validation Team	Xu Sijia 徐思佳	我已审核了此方案，同意其内容，并同意提供所需的质量资源来完成此次验证。 I have reviewed the contents of this protocol agree with the contents, and agree to provide quality resources needed to complete the validation protocol.
TS Manager 技术部经理	验证工作小组成员 Member of Validation Team	Ji Wenlong 吉文龙	我已审核了此方案，同意其内容，并同意提供所需的资源来完成此次验证。 I have reviewed the contents of this protocol agree with the contents, and agree to provide resources needed to complete the validation protocol.
Production Manager 生产部经理	验证工作小组成员 Member of Validation Team	Chen Guangxu 陈光圩	已审核了此方案，同意其内容，并同意提供所需的资源来完成此次验证。 I have reviewed the contents of this protocol agree with the contents, and agree to provide resources needed to complete the validation protocol.
General Manager 总经理	验证总负责人 Total Validation Leader	Zhang Yehua 张叶华	我已审核了此方案，同意其内容，并同意提供所需的资源和技术支持来确保此次验证成功。 I have reviewed the contents of this protocol agree with the contents, and I agree to provide the resource & technical support needed to ensure its success.

4. 验证策略 Validation Strategy

4.1.半周期循环确认的原因采用预先设定的灭菌循环参数实现产品指定的无菌保证水平。

The reason for performing the Half Cycles Qualification is to achieve the defined SAL using predetermined the sterilization cycle parameters.

4.2.此次方案验证策略遵循 ISO11135-2014 中的“过度杀灭法”。

The validation strategy for this protocol will follow the " overkill approach" described in ISO 11135:2014.

4.3.验证活动的范围 Scope of Activities:

4.3.1. 过程挑战装置有效性 PCD Rationale

基于短周期确认的结果确定合适的过程挑战装置(PCD -产品硅胶圆形开槽管 15Fr 带引导针 3/4（粘接），将此产品用于内置过程挑战装置（IPCD）的制备来评估预先设定的灭菌过程。

Based on the fractional cycle results to determine the appropriate PCD (PCD - JP CHAN DRN SIL RND 15FR 3/4 W/TRO,and this product will be used for building the IPCD for assessment of the predetermined sterilization process.

4.3.2. 将运行三个半周期以确认无菌保证水平能够达成。

Three half cycles will be conducted to confirm the achievement of the SAL 10^{-6} 。

4.3.3. 采用灭菌暴露时间为常规灭菌时间一半的三个半周期灭菌循环-在灭菌柜内灭菌，证明所有的生物指示剂（植入在过程挑战装置内，内置挑战装置）都被杀灭（生物指示剂的菌落数≥1.0×10^6）。EPCD 部分杀死可以接受。

Total inactivation of Biological Indicators (BIs) in a defined IPCDs, with a population of not less than 1.0×10^6 spores/strip, shall be demonstrated using three half cycles at half of the EO exposure time of the predetermined EO sterilization cycle. Partial EPCDs showed growth is acceptable.

4.4.无菌保证水平的要求 Sterility Assurance Level Requirements.

需证明无菌保证水平达到 10^{-6}

Sterility Assurance Level of 10^{-6} would be demonstrated for the product.

4.5.此次验证需提供文件证明在满载条件下指定装载在指定装载的灭菌柜，指定的灭菌循环中可交付的物理参数。

The validation will provide documented evidence of the delivery of the physical parameters

for a defined load in a predetermined sterilization cycle for the listed products in a loaded sterilization chamber.

4.6.半周期确认活动包灭菌柜温度，湿度和压力测量，装载的温湿度测量以证实在指定的过程条件下操作，灭菌柜能重复性交付的指定灭菌过程。同时证明微生物杀灭性。

The Half Cycles Qualification consists of the validation load temperature, RH profile, pressure measurements to demonstrate that the sterilization chamber can reproducibly deliver the predetermined sterilization process. It also demonstrates microbiological lethality of the process.

5. 接受标准 Acceptance Criteria

5.1.半周期 Half Cycle

5.1.1. 所有在内置挑战装置内的生物指示剂，除阳性对照之外，必须失活。EPCD 部分可以生长。

All BIs in the internal Process Challenge Device (IPCD), with the exception of positive controls, shall be deactivated.Partial EPCD can show growth.

标注：“失活”定义为生物指示剂生长阴性，生物指示剂生长阳性且通过调查证实污染来自于灭菌后，可以认为是可接受的。

Note: “Deactivated” is defined as negative for growth of the biological indicator (BI) organism.Units that are positive due to growth of a contaminant can be deemed acceptable if an investigation concludes that it was the result of post sterilization contamination.

5.1.2. 阳性对照测试物需生长阳性。

Positive control test articles shall be positive for growth, thereby demonstrating the adequacy of the recovery technique.

5.1.3. 灭菌暴露时间不能超过指定全循环所需的灭菌暴露时间的一半。

EO exposure time must be no more than half of the minimum required EO exposure time for the predetermined sterilization cycle.

5.1.4. 附录 1 的灭菌参数必须符合。

Cycle parameters as programmed per Appendix 1 for the half cycle must be met.

6. 偏差处理 Deviations Handling

所有的偏差需要进行评估以确认它们对验证循环可接受性的影响。可接受的理由需记录在偏差报告中，并被此方案和报告的批准者批准，此文件需包含再再确认最终报告中。

All deviations to the defined requirements shall be evaluated as to their impact on the acceptability of the half cycle qualification run. Rationale for acceptance shall be documented in the deviation format and approved by the same personnel as those approving the protocol and report. This documentation shall be included in the qualification completion report.

7. 参考 References

7.1. ISO 11135:2014 医疗器械灭菌-环氧乙烷-医疗器械灭菌的发展，验证及常规控制的要求。

7.2. ISO11135:2014 Sterilization of health care products-Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices”

7.3. ISO10993-7:2008 EO 残留 ISO10993-7-2008 Ethylene oxide sterilization residual

7.4. ISO10012, Measurement management systems 测量仪器系统，测量过程及测量设备的要求— Requirements for measurement processes and measuring equipment

7.5. ISO 11138-1:2017, Sterilization of health care products 医疗保健产品的灭菌，生物指示剂，部分 1-总的要求-Biological indicators -Part 1: General requirements

7.6. ISO 11138-2:2017, Sterilization of health care products 医疗保健产品的灭菌，生物指示剂，部分 2-EO 灭菌过程的生物指示剂-Biological indicators- Part 2: Biological indicators for ethylene oxide sterilization processes

7.7. ISO 11140-1:2014, Sterilization of health care products 医疗保健产品的灭菌，化学指示剂，部分 1:总的要求-Chemical indicators -Part 1: General requirements.

7.8 AAMI TIR15-2016,Physical aspects of ethylene oxide sterilization.环氧乙烷灭菌的物理性方面。

工厂的规范性文件 Site Specific Documents.

文件编码 Document No.	文件题目 Document Title
JCQ 品 20029	无菌试验作业指导书 Instruction of sterility test
JCQ 品 20050	初始污染菌作业指导书 Instructions for the operation of initial contaminated bacteria

JCQ 生 10009	灭菌作业指导书 Sterilization operation instruction
BQ260	灭菌验证程序 sterilization validation procedure

8. 程序 Procedure

8.1.前提步骤 Prerequisite Steps

8.1.1. 在实施确认活动前参与与实施此方案的所有人员需进行相应的培训，且培训记录需附在最终报告中。

All personnel involved in the execution of this protocol shall be trained and requirements prior to carrying out the Half Cycles Qualification activities and the training is to be documented on the training session record shall be attached to the completion report.

8.1.2. 所有无线探头的校验记录/结果，安装在灭菌柜上的温度，湿度和压力探头在实施验证活动前需审核以确认其可接受性。

All calibration records/results of data loggers (Temperature/Relative Humidity data loggers), temperature,RH probes and pressure transmitter fixed to the sterilization chamber shall be reviewed for acceptance prior to carrying out the performance qualification activities.

8.1.3. 审核设备维护记录，预防性维护记录需记录。

Review of equipment maintenance records shall be done and the status of the preventive maintenance will be recorded.

8.2.设备 Equipment

8.2.1. 需验证的灭菌柜安装在工厂的灭菌车间内

The sterilization Chamber that will be validated is installed in the plant EO workshop.

8.2.2. 尺寸 Dimensions.

8.2.2.1. 灭菌柜腔体内部尺寸 Sterilizer Internal dimensions：L - 2800mm, W - 1350mm, H - 1700mm，腔体体积 Chamber Volume ：6m^3 ，模拟产品装载体积 Dunnage Product Load Volume: 4.1 m^3。

8.2.3. 已校验的无线探头用于产品装载温湿度的监控

Calibrated wireless data loggers to be used to monitor load temperature and humidity.

8.3.材料 Materials

8.3.1. 装载 Load

所罗列的产品中，产品 24Fr 硅胶引流管装载密度最大（142.188kg/m^3），故此产品工程样品可以用于此次产品的模拟装载进行短周期确认（密度≥142.188 kg/m^3）。

Among the listed products, product 24Fr Silicone Drainage Product represents the highest loading density (142.188 kg/m^3), so this time the engineering product will be built for the dunnage load (density≥ 142.188 kg/m^3) for this fractional cycle qualification .

8.3.2. 过程挑战装置 PCDs

8.3.2.1. 内置过程挑战装置 IPCD - 产品硅胶圆形开槽管 15Fr 带引导针 3/4（粘接 ），并且植入生物指示剂（枯草芽孢杆菌）将用于此次半周期循环确认。

Internal PCD (IPCD - JP CHAN DRN SIL RND 15FR 3/4 W/TRO), inoculated with biological indicator (Bacillus atrophaeus) will be used for this Half Cycles Qualification.

8.3.2.2. 平均孢子菌落数至少大于等于 1.0×10$^{6/}$条，在 54℃ 生物指示剂的 D 值需大于等于 2.5 分钟.

The average spore concentration would be at least ≥1.0×10^6/strip and the D value of the BI should be >2.5 minutes at 54° C.

品牌/型号 Brand/Type	菌株 Microorganism	菌落数 BI population/strip	D-value D 值	供应商 Manufacturer
富捷/EOS-E6 Fujie/EOS-E6	ATCC 9372	≥1.0 x 10^6/strip	≥2.5min	杭州富捷消毒用品有限公司 Hangzhou Fujie Disinfection Products Co., Ltd

8.3.2.3. 每个植入生物指示剂的产品将被包装入初始包装中并加以密封。

Each inoculated product is then packed into a primary packaging and sealed.

8.3.2.4. 依照要求进行内置挑战装置，外置挑战装置的制备，放置及回收,确认每个包装好的过程挑战装置都有正确的标识.

Identify all the packed PCDs with proper marking per the requirements of IPCD and EPCD preparation, placement and retrieving.

8.4. 定义半周期循环

Define the predetermined half cycle runs

8.4.1. 准备产品装载 Construction and staging of load

8.4.1.1. 产品装载将按附录 2（半周期）进行准备，再移入冷库冷冻至少 12h,模拟最恶劣的条

件，以上方可进行半周期循环。

The load will be configured in the sterilization chamber as per appendix 2 for half cycles ,the validation load will be transferred to the the freezer to storage for at least 12h simulating the worst case condition before half cycle runs.

8.4.1.2. 产品装载将植入温湿度无线探头，内置过程挑战装,外置过程挑战装置。所有的过程挑战装置及探头依照附录 2 半周期的图示放置在满载的产品箱中。

The load will be seeded with temperature and humidity data loggers, IPCDs,EPCDs, all PCDs and sensors will be placed into the full load shipping cartons per Appendix 2 for half cycles.

8.4.1.3. 依照 ISO 11135:2014 的建议，基于产品装载体积 4.1 m³，半周期循环最少需要 15 个（实际 18 个）个内置过程挑战装置，并且标记为 B1-B18， EPCD 共计 18 个，标记为 EB1-EB18，按照附录 2 的要求分布在灭菌装载中。

As per the recommendation of ISO 11135:2014, a minimum of 15units of IPCD (actual 18 units) are required for the half cycle (based on the product load volume-4.1m^3). The IPCDs will be labeled as B1-B18 will be distributed throughout the sterilization load according to appendix 2,accordingly18 units of EPCD are require,labeled EB1-EB18,and will be fixed outside of the shipping cartons.

8.4.1.4. 依照 ISO11135:2014 的建议，基于产品装载体积，至少需要 5 个温度探头(实际 6 个）和 2 个湿度探头（实际 3 个），（标识 T-T6。H1-H3）用于半周期循环。探头将均匀分布于产品装载中，依照附录 2 放置在指定的纸箱中。

As per the recommendation of ISO 11135:2014, a minimum 5 units of temperature sensors(actual 6, labeled T1-T6) and a minimum 2 units of humidity sensors (actual 3,labeled H1-H3) are required during the half cycle runs (based on the product load volume 4.1m^3). Sensors will be uniformly distributed throughout the load. These sensors shall be placed inside the specified cartons according to the appendix 2 .

8.4.2. 灭菌循环的时间按排 Timing of sterilization runs

8.4.2.1. 模拟产品装载将用于此次半周期循环确认，包含 3 个半周期。每个循环之间的时间间隔至少 3 天以便于模拟装载充分解析,防止残留的杀灭作用和员工安全。

Non-saleable dunnage products will be used for this Half Cycle Qualification, including three

half cycles . The time interval of each cycle shall be at least 3 days in order to let the dunnage load being sufficient aerated to prevent residuals kill and employees safety.

8.5.半周期 Half Cycles

8.5.1. 需运行三个半周期循环 Three half cycles shall be run.

8.5.2. 依照附录 2 放置内置挑战装置，外置挑战装置及温湿度探头

Place the IPCDs,EPCDs and T/RH data loggers as per Appendix 2

8.5.3. 按照附录 1 的参数要求运行半周期灭菌循环，半周期的参数除灭菌暴露时间外与常规灭菌循环参数相同，灭菌暴露时间与常规灭菌循环相比缩减一半，灭菌温度及 EO 用量取设定值下限。

Process the staged load per the sterilization cycle parameters in Appendix1. The parameters of the half cycle will be the same as the parameters to be used for full/routine sterilization processing with the exception of exposure dwell time. The gas exposure dwell time for the half cycle will be reduced by 50% as compared to the full cycle.And the sterilization temperature and EO usage will adopt the lower setting limit .

8.5.4. 半周期灭菌循环结束后，将产品装载移至后灭菌区域，从产品装载的指定位置回收无线探头，EPCDs，IPCDs。所有的内置过程挑战装置和外置挑战装置将在规定的时间间隔内移交给微生物室做 BI 培养。

After completion of the half cycle, move the load into the post sterilization area to retrieve the data loggers, EPCDs, IPCDs from the established locations in the load. All IPCDs, EPCDs will be handed over to microbiology lab for incubation within the predefined time interval.

8.5.5. 记录内置过程挑战装置，外置挑战装置中 BI 的培养结果。

The processed IPCDs, EPCDs shall be tested for BI incubation and results shall be recorded.

8.5.6. 下载无线探头内的数据,进行分析。

Download the data from data loggers, plot the temperature and RH profiles, and perform data analyses.

8.6.数据收集 Collection of Data

8.6.1. 收集下列信息或记录 Collect at least the following information or records:

8.6.2. 列出用于装载的产品（产品描述，产品编号和数量）。

List of products used in the load (product description, catalogue/code number and quantity).

8.6.2.1. 灭菌车间人员负责收集灭菌批记录。

Sterilization runs record (cycle printout) will be collated by ETO staff.

8.6.2.2. 微生物测试结果，包含样品识别，设备识别，培养基识别，培养温度及时间。

Microbiological test results for each set of test articles, including sample identification, equipment identification, medium identification, incubation temperatures and times.

8.6.2.3. 灭菌车间人员负责探头数据表的完成（温湿度分布数据）

Tabulation of sensor data (i.e. temperature and humidity profile data) will be retrieved by ETO staff.

8.6.2.4. 灭菌循环概述，包含灭菌循环的处置

Run summary sheet, including disposition of the run.

8.6.2.5. 方案作者负责测试数据收集及编纂以完成验证报告

All testing data will be collected by the protocol author and compiled for the validation completion report.

8.7. 数据审核 Review of the data

8.7.1. 循环记录 Runs Records

8.7.1.1. 灭菌循环报告需经由灭菌人员及质量代表审核以确保符合指定的过程参数。

Cycle printouts from the associated qualification runs shall be reviewed by both sterilization staff and quality representative to ensure that the specified cycle parameters have been met.

8.7.2. 探头数据 Sensor data

8.7.2.1. 编纂的探头数据需经由灭菌人员及质量代表审核确保报告数据真实性。

Sensor data compiled for reporting purposes shall be reviewed by both EO staff and quality representative to ensure that the reported data is reflective of the raw data collected during the periods of interest.

8.8. 实验室测试数据 Laboratory testing data

8.8.1. 实验室测试数据须由质量经理审核以符合程序要求

Forms and worksheets used to collect data from laboratory testing shall be reviewed by quality manager to ensure compliance with the governing procedures.

8.9.产品处置 Disposition of the products

8.9.1. 用于此次性能验证的装载为模拟装载，不存在产品处置要求。

The load used in this PQ run are non-saleable dunnage load, there is no products disposal requirements.

8.10.完成半周期确认报告 Completion Report

8.10.1. 完整的验证报告将具体的验证测试结果，下列事项将包含在报告中或支持数据中。

A completion report detailing the results of the half cycle qualification activities will be generated. The following items will be included in the report and/or in the supporting data:

8.10.2. 灭菌批记录 Sterilization cycle run records.

8.10.3. 定义装载方式及用于性能确认的最大密度。

Definition of loading pattern(s) and maximum density used in the PQ

8.10.4. 物理性参数 Load physical performance profile.

8.10.5. 产品装载进入灭菌柜的最低温度。

Minimum product load temperature to enter the sterilization chamber

8.10.6. 在灭菌暴露阶段腔体的最低温及最高温。

Minimum/Maximum temperature of chamber during EO exposure time

8.10.7. 预处理结束，灭菌暴露阶段和解析阶段的温度差距，最低温和最高温的位置。

Temperature spread and locations of minimum and maximum temperature at the end of conditioning, throughout EO exposure and aeration.

8.10.8. 灭菌暴露时间 EO exposure time.

8.10.9. 在气体注入阶段的压力上升数值和灭菌后清洗。

Pressure rise during gas injection and post sterilization flushing

8.10.10. 生物指示剂及产品无菌测试结果，产品初始生物负载。

A summary of results from incubation of biological indicators , product bioburden tests.

8.10.11. 实施的灭菌循环的概述，包含实际值与参数设定值间的差异。

A summary of executed cycles, reporting the actual values or ranges for the parameters listed in the sterilization cycle parameters

8.10.12. 灭菌循环参数设定及公差范围。

Sterilization cycle specifications for routine production including set points and tolerances.

8.11. 生物指示剂分析证书 Biological Indicator Certificate(s) of Analysis.

8.12. 灭菌剂分析证书 Certificate of Analysis for the sterilant used in the process

8.13. 半周期确认相关人员的培训记录 Training records of related staff on this PQ protocol.

8.14. 偏差的解决方法及相关的调查结果

Resolution of any deviations and the results of any related investigations.

8.15. 半周期确认方案，完整的报告及支持性数据将予以存档

Half Cycles Qualification Protocol, completion report, and supporting data will be managed and archived according to the requirements of the plant documentation procedure。

9. 附录 Appendices

预先设定的灭菌循环参数 Predetermined sterilization cycle parameters

9.1. 附录 1 图示半周期/全周期循环 Half Cycle/Full Cycle - Appendix 1

9.2. 附录 2 图示托盘图示说明测试样品（半周期）

Pallet diagram indicating location of all test articles (for half cycle)-Appendix 2

9.3. 附录 3 图示说明 IPCD 及 EPCD

Pictures diagram indicating IPCDs and EPCD.

Device Manufacturing Co;Ltd

医疗器械有限公司

图示短周期循环参数 Fractional Cycle Parameters- Appendix 1

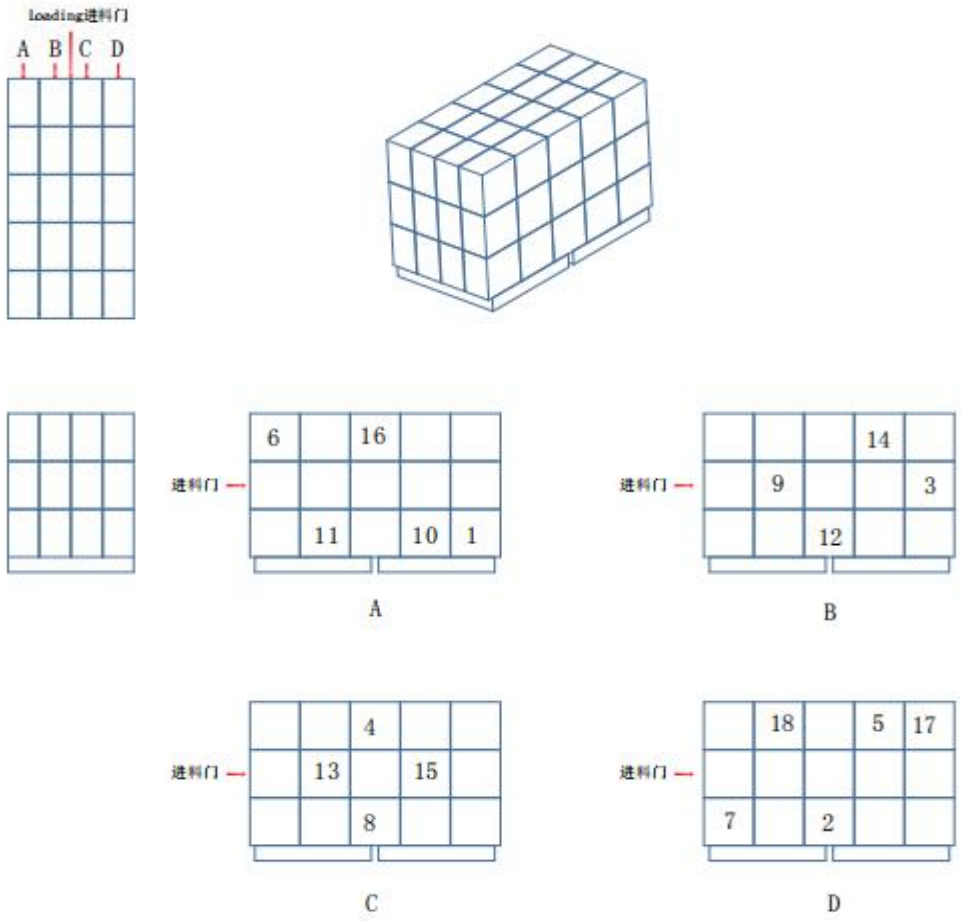
灭菌日期 Date　　批号 Lot number　　灭菌循环号：Cycle No.

产品 Product

阶段 Phase	设置 Setting	范围 Range	实际值 Actual value
1.Min. Temperature entering the sterilizer (℃)最低进入灭菌柜的温度	TBD	TBD	
2.Preheating 预热			
Temperature (℃)温度	50℃	50-56℃	
Heat Dwelling Time(min.)保温时间	60min.	60min.	
3.Initial vacuum (kpa)初始真空度	-70kpa	-71 - -69kpa	
Time 时间	12-14min.	12-14min.	
4.Pressure holdingTime（min.)保压时间	5min	5min	
5.Leakage test 测漏	≤0.3kpa/min.	≤0.3kpa/min.	
6.Humidify 加湿	1 time	1 time	
加湿压力	3kPa	2.5-3.5kPa	
7.EO gas injection 加药			
加压力变化值	28-32kPa	28-32kPa	
EO gas weight (kg)加药重量	4kg	4-6kg	
Time 时间	10-16 min.	10-16 min.	
EO concentration EO 浓度	610mg/L	610-650mg/l	
Half cycle(min.)半周期	180min.(predefined)	180min.(predefined)	
Full cycle(min.)全周期	360min.(predefined)	360min.(predefined)	
8.Post vacuum flushing 灭菌后清洗			
Vacuum Pressure (kpa)抽真空压力	Approximate -70kpa	Approximate -70kpa	
Air washing Pressure (kpa)放空压力	Approximate -5kpa	Approximate -5kpa	
Rinse times 清洗次数	5	5	
Air inbleed 空气平衡	≥-3kpa	≥-3kpa	

附录 2 图示托盘图示说明测试样

Pallet diagram indicating location of all test articles -Appendix 2



备注 Remarks：

1．1~18 号的箱子里面放置对应的 1 到 18 内部 IPCD，箱子的外面对应 1 到 18 个外部 EPCD。B1-B18 placed inside the shipper cases according to the diagram indicated, and EPCDs are fixed outside of the accordingly shipper cases .

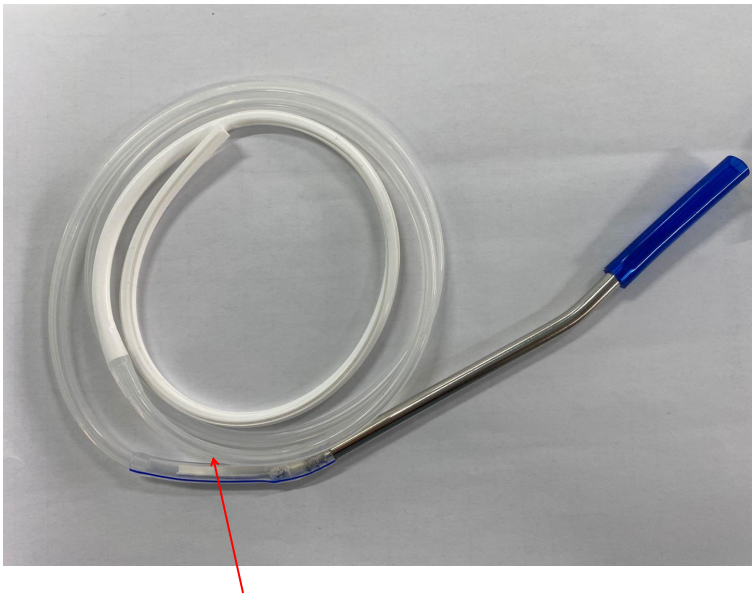
2． 1~6 号的箱子里面放置对应的 1 到 6 号的温度记录仪，湿度为 1，4，6 号（和内部 IPCD 放置在一起）。

Temperature data loggers and RH data loggers are placed inside the shipper cases according to the diagram indicated.

附录 3 图示说明 IPCD 及 EPCD

Pictures diagram indicating IPCDs and EPCD - annex3.

1. 内置挑战装置 - 硅胶圆形开槽管 15Fr 带引导针 3/4（粘接）
IPCD - JP CHAN DRN SIL RND 15FR 3/4 W/TRO-IPCD2

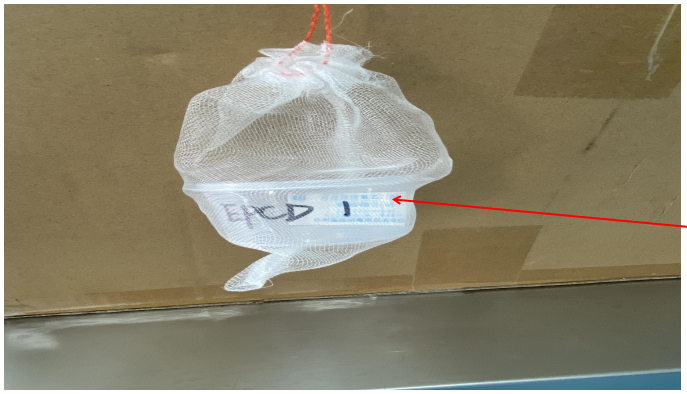


BI position 生物指示剂位置

2. 外置挑战装置孢子条密封在塑料瓶子内

EPCD -BI strip seeded in the plastic pot

厚度 thickness：0.35±0.05mm



BI position 生物指示剂位置