**OPERATION QUALIFICATION  
运行确认**

|  |  |
| --- | --- |
| **SUPPLIER NAME/供货商:**  **Shanghai Tofflon**  **Medical Equipment Co., Ltd.**  **上海东富龙医疗装备有限公司** | **CUSTOMER NAME/客户名称:**  **Tingo Regenerative Medicine (Tianjin) Technology Co., Ltd.**  **天九再生医学(天津)科技有限公司** |
| **NO. /编号：**  **2021-006Yd-OQ** |
| **MODEL/型号: LNS102B** |
| **OPERATION QUALIFICATION FOR AUTOMATIC LIQUID NITROGEN STORAGE SYSTEM 全自动液氮存储系统运行确认** | |

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**Operation Qualification for Automatic Liquid Nitrogen Storage System  
全自动液氮存储系统运行确认**

**The signatures below indicate approval of this protocol and its attachments and indicate that it is ready for execution. Any changes or modifications to the intent or the acceptance criteria of this protocol, following approval, requires the generation of an amendment which must be approved prior to execution.  
下面的签名表示批准本文件及其附件，且表明已经为执行作好了准备。在批准后，任何对本档的原意或验收标准而进行的改变或修正都必须提供补充档，并在执行以前必须取得批准。**

**Document Approval文件批准**

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| --- | --- | --- | --- | --- |
|  | **Department**  **部门** | **Name**  **姓名** | **Signature**  **签名** | **Date**  **日期** |
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|  |  |  |  |
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| **Approved by批准** |  |  |  |

**Version History 版本历史**

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| --- | --- | --- |
| **Version 版本** | **Issued date 颁布日期** | **Reason for new issue 颁布原因** |
| **V 1.0** |  | **Initial issue首次发布** |

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1. Purpose目的

The purpose of Operational Qualification (OQ) is to establish, through documented testing, that all critical components are capable of operating within established limits and tolerances. It is the process of testing to ensure that individual components and systems operate as specified, and how that information is recorded. OQ is an activity that is regulated by the Current Good Manufacturing Practice, and is a part of final qualification activities before Process Validation begins.  
运行确认的目的是通过测试证明所有关键部件能够在已制定的界限及承受能力下运行。这是一个测试的过程，来确保独立部件和系统能够按照规定运行，并记录信息。运行确认是cGMP规定进行的活动，它是在工艺验证开始之前确认活动的一部分。

1. Scope范围

This document is applicable to Automatic liquid nitrogen storage system, model LNS102B, project number 2021-006Yd for the end user.  
本文件适用于天九再生医学(天津)科技有限公司，型号为LNS102B，项目编号2021-006Yd的全自动液氮存储系统。

1. Abbreviations缩略语

| Abbreviations 缩略语 | Definition 定义 |
| --- | --- |
| OQ | Operation Qualification 运行确认 |
| GMP | Good Manufacturing Practice 药品生产质量管理规范 |
| NMPA | National Medical Products Administration  国家药品监督管理局 |
| ISO | International Organization for Standardization 国际标准化组织 |
| Tofflon | Shanghai Tofflon Medical Equipment Co., Ltd.  上海东富龙医疗装备有限公司 |

1. Responsibility职责

**Responsibilities of Shanghai Tofflon include but not limited to  
Tofflon的职责包括但不仅限于**

* Draft the OQ protocol   
  编写OQ方案；
* Submit the OQ Protocol for customer to review and approve  
  提交OQ方案，以供用户进行审核和批准；
* Record the deviations found during the OQ  
  记录在OQ过程中发生的偏差；
* Collect the relevant basic technical materials  
  收集相关的基础技术资料;
* Propose solutions to the deviations  
  针对偏差提出解决方案;

**Responsibilities of customer include but not limited to  
客户的职责包括但不仅限于**

* Review and approval OQ Protocol  
  审核并批准OQ方案
* Assistant to record and handle the deviation/change occurred during OQ;  
  协同记录和处理OQ过程中发生的偏差/变更；
* Assistant to collect raw data and fill in relevant check table;  
  协同收集原始数据并填写相关表格；
* Provide the provision of necessary human resource and equipment;  
  提供为此次执行本方案所必要的资源（包括人力资源、设备运行资源）；
* Review and approve the final conclusion.   
  审核和批准最终结论。

1. References参考文件

* China GMP (2010)   
  《药品生产质量管理规范（2010年）》
* Technical proposals  
  技术说明
* ISBER\_Best\_Practices\_3rd\_Edi   
  国际生物和环境样本协会生物样本库最佳实践第三版
* China Medical Biotechnology Association Biobank Standards (Trial)  
  中国医药生物技术协会生物样本库标准（试行）
* GBT 14174-2012 Large-caliber liquid nitrogen container.  
  GBT 14174-2012 大口径液氮容器

1. System Description系统说明

The automatic liquid nitrogen storage system includes functional modules and devices such as working chamber, storage tank, working area refrigeration system, arm assembly, sample detection system, transfer cabin, sample tray inlet and outlet mechanical system, storage rack positioning mechanical system, touch screen, defrost system and manual intervention device. Storage tank keep the gaseous nitrogen environment under -150 ℃, samples can be stored in the storage tank of movable trays, through automation machinery, achieve tray in storage tanks and cabin automatically between in and out of work, and work in the tank corresponding workspace samples by using mechanical arm, automatic sorting access operation. The refrigeration system is used to ensure that the temporary sample sorting operation is below the cell safety temperature in real time and to ensure the operation reliability of mechanical and electrical components.  
全自动液氮存储系统包括工作舱、存储罐、工作区制冷系统、机械臂总成、样本检测系统、传递舱、样本托盘进出机械系统、存储架定位机械系统、触摸屏、除霜系统、人工干预装置等功能模块和装置。存储罐内保持-150℃以下的气相氮气环境，样本可以长期存储在存储罐内的可活动托盘内，通过自动化机械装置，实现托盘在存储罐和工作舱之间的自动进出，并在工作舱相应工作区利用机械臂实现样本自动分拣存取作业。制冷系统用于确保样本临时分拣作业实时处于细胞安全温度以下并确保机械、电气元件的运行可靠性。

The system includes a transfer compartment for transferring materials in and out, a working compartment for sorting and accessing samples by mechanical arm, and a storage tank for sample storage.

本系统包括一个用于传递物料进出的传递舱和一个利用机械臂实现对样本的分拣存取的工作舱，还有一个用于样本存储的存储罐。

|  |  |
| --- | --- |
| **Relevant Section 对应区域** | **Description 描述** |
| Pass-box chamber 传递舱 | Used to transfer materials in and out  用于传递物料进出 |
| Working chamber 工作舱 | It is mainly used for palletizing in and out and for sorting and accessing samples by mechanical arm  主要用于托盘进出和利用机械臂实现对样本的分拣存取 |
| Storage tank 存储罐 | It is mainly used to store the target samples in low temperature environment  主要用于将目标样本的存储于低温环境 |

1. Good Documentation Practice文件管理规范

**Recording Pens 记录用笔：**

* Choose nonfading ink pens or marker pens. Blue pens are recommended.  
  使用不消褪的墨水笔或记号笔，推荐使用蓝色笔记录

**Signature 签名：**

* Only authorized persons can sign on any documents.  
  被授权的人员才能签署文件
* Unless otherwise specified, the full name shall be used as the signature.  
  应签全名，除非文件另有规定
* The signature shall be readable.   
  签名应该是可辨认的
* The signatures shall be consistent.   
  签名应始终一致

**Column Filling 填写栏目：**

* All the columns shall be filled.  
  所有栏目必须填写
* The full text shall be filled if it is the same as that in the field above.  
  填写内容与上面栏目相同应重新填写
* If there is nothing to be filled in to an individual field, N/A (abbreviation for not applicable) shall be written in this field.  
  若有单个栏目不需要填入内容，则在空白处填写英文字母“不适用”的简写“N/A”，以表示无此项内容。
* If there is nothing to be filled in more than one neighboring fields, such fields shall be crossed with a diagonal line, with “N/A” noted above the line and the signature and the date noted below the line. The signature and the date shall be written along the line on the same side as much as possible.  
  填写记录时，若有多个栏目不需要填入内容，应用斜线划掉，斜线上方填写“N/A”，下方签名和注明日期。签名及日期应尽量沿斜线同侧填写。

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|  | N/A |  |  |
|  | 签名日期 | Signature date |  |

**Correction of Mistakes 更改错误：**

* When any mistakes are to be corrected immediately after the document has been complete, the correct record shall be entered and signed and dated. The original information shall be left clearly readable.   
  For example:  ~~January 1, 2010,~~ signature and date  
  文件刚完成，立即更改的，在错误处划线，填入正确的，签名和注明更改日期，确保原先信息仍清晰可识别  
  如：~~2010.01.01~~ 签字，日期
* When any mistakes are to be corrected afterwards, besides conforming to the above requirements, the reasons for the correction must be noted and the possible influences shall also be assessed and noted.   
  事后更改的，除非立即更改的要求外，还应注明更改的原因，检查和注释可能的影响。

**Date Recording Format 记录日期：**

* Four digits shall be used for the indication of the year, two digits for the month and another two for the date.   
  年用4位数表示，日和月用2位数表示
* For example: 2009.09.01   
  如：2009.09.01

**Use of Abbreviations 使用缩略语：**

* An abbreviation shall be noted in brackets immediately after the full name before it can be used in the rest of the document.  
  在术语全称后的括号内注明缩写，然后才可以使用缩写。

**Written Words and Names 书面语及名称：**

* Standard written words and names shall be used.   
  使用规范的书面语及名称
* The names shall be consistent all through the document.   
  文件前后名称要一致

1. Testing List测试列表

|  |  |
| --- | --- |
| Test No. 编号 | Test Name 名称 |
|  | Prerequisites  先决条件 |
|  | Test instruments calibration Qualification  测试用仪器仪表校准确认 |
|  | SOP Qualification  SOP确认 |
|  | IQ Punch List Closeout Qualification  IQ遗留清单关闭确认 |
|  | Access control test  权限控制测试 |
|  | Sample automated access testing  样本自动化存取测试 |
|  | Access Sorting Operation Test  存取分拣作业测试 |
|  | Alarm test  报警测试 |

1. Personnel Identification人员确认

All the personnel involved in the protocol must sign in the following form before the initiation of OQ. Personal must be trained to ensure that competent operational qualification work.  
在OQ开始前，本方案涉及的所有人员必须在下表签字。参加确认的人员必须经过培训，以保证胜任OQ工作。

**Personnel Qualification  
人员确认**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name 姓名 | Signature 签名 | Department  部门 | Title 职务 | Date 日期 |
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1. Testing Procedures测试程序

## **Prerequisites先决条件**

**Purpose目的**

All prerequisites necessary to the OQ execution have been satisfied.  
所有进行OQ的先决条件已经得到满足。

To ensure that the personnel involved in the protocol are all trained.  
确认参与此方案的人员都已经过培训。

**Acceptance Criteria可接受标准**

All the prerequisites must be satisfied before the beginning of the execution of OQ.  
开始执行OQ之前，所有的先决条件必须得到满足。

All persons involving in this protocol must be trained.  
参与此方案的人员都必需经过培训。

**Procedure程序**

Verify that OQ protocol has been approved.  
确认本方案已得到批准。

There should be a documented training for all people involved in the tests before initiation of OQ.  
在OQ开始前，对所有参与测试的人员进行培训，培训应该有记录。

**Prerequisites  
先决条件**

|  |  |  |
| --- | --- | --- |
| Prerequisites 先决条件 | | Yes/No 是否符合要求 |
| OQ has been approved OQ已经得到批准 | OQ for Automatic liquid nitrogen storage system 全自动液氮存储系统运行确认  Document No.文件号：  Version No.版本号： | Yes ( ) No ( ) |
| All people involved in the tests has been trained and recorded. 所有参与测试的人员已经过培训并有记录。  Att. ID附件编号： | | Yes ( ) No ( ) |

***Conclusion & Remarks结论和备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **T****est instruments calibration Qualification测试用仪器仪表校准确认**

**Purpose 目的**

Verify that each test instrument that will be used during execution of the OQ tests has been calibrated.   
确认执行OQ测试中使用的所有仪器都经过校准。

**Acceptance Criteria可接受标准**

The testing instruments for OQ have been calibrated and are within the calibration due date.  
OQ测试使用仪器仪表均经过校准，且在有效期内。

Measurement standard for calibration can be traced back to China National Standards of Measurement.  
用于校准的计量标准应该能够追溯到中国国家计量基准。

**Procedure程序**

Record the name, serial No., model, the calibration certificate No., calibration dates, and the next calibration expiration date of instruments used for OQ tests, and attach calibration certificate. Check whether it can be traced back to China National Standards of Measurement. And check whether it can be traced back to China National Standards of Measurement.  
记录OQ测试用仪器仪表名称、序列号、型号、校准证书编号、校准日期以及有效期至，并附上仪器校准证明。检查是否能够追溯到中国国家计量基准。

**Test Instruments Calibration Qualification  
测试用仪器仪表校准确认**

| Instruments Name 仪器仪表名称 | Manufacture 生产厂家 | Serial No. 系列号 | Model 型号 | Calibration Certificate No. 校准证书编号 | Calibration 校准 | |
| --- | --- | --- | --- | --- | --- | --- |
| Cal. Date 校准日期 | Expiry Date 有效期至 |
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***Conclusion&Remarks结论和备注***

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| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **SOP Qualification SOP确认**

***Purpose 目的***

Verify the documents for operational and maintenance of Automatic liquid nitrogen storage system.  
确认全自动液氮存储系统运行及维护所需的SOP文件状态。

***Acceptance Criteria可接受标准***

The documents for operational and maintenance of Automatic liquid nitrogen storage system had been approved.  
全自动液氮存储系统运行及维护所需的文件已批准。

***Procedure程序***

Check that the SOPs needed for operational and maintenance of Automatic liquid nitrogen storage system are available and they have been approved.  
检查全自动液氮存储系统运行和维护所需要的SOP是否都存在，并确认其处于已批准状态。

Record the document informations in the table, here including the Doc. Name, No. and Version No., and Review&Approval Status.  
将文件信息记录在表格中，包括文件名称、编号、版本号及签批状态。

**SOP Qualification  
SOP确认**

|  |  |  |  |
| --- | --- | --- | --- |
| Doc. Name 文件名称 | Doc. No. 文件编号 | Ver. No. 版本号 | Status 状态 |
|  |  |  | Approved已批准 ( ) Draft 草稿 ( ) |
|  |  |  | Approved已批准 ( ) Draft 草稿 ( ) |
|  |  |  | Approved已批准 ( ) Draft 草稿 ( ) |
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|  |  |  | Approved已批准 ( ) Draft 草稿 ( ) |
|  |  |  | Approved已批准 ( ) Draft 草稿 ( ) |

***Conclusion/Remarks结论/备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **IQ Punch List Closeout Qualification IQ遗留清单关闭确认**

**Purpose 目的**

To verify the issue which were documented during the IQ, and required to be verified during OQ had been addressed.  
确认执行IQ过程中记录的需要遗留到OQ阶段进行确认的遗留项目及其他事项已经得到解决。

**Acceptance Criteria可接受标准**

The issues identified during IQ and which should be verified during OQ had been appropriately addressed as per the resolution listed next to each issue.  
在IQ活动中确定的需要在OQ阶段进行确认的遗留项目已经按照每一遗留项目旁边的应对措施进行了解决。

**Procedure程序**

Obtain a copy of Punch List of IQ.  
取得IQ测试的遗留清单的复印件。

Review and remark each item which shall be verified during OQ and verify it had been appropriately “closed” as per the resolution listed in Punch List.  
逐一审核，确认每一项遗留到OQ的项目均已得到合适的解决并关闭，并在该遗留清单中进行标注。

Some issues which are required to be verified in the following work, such as the PQ, shall be not as the veto items for this test and they shall be documented in the Punch List of OQ and verified in following work.  
某些遗留项目需要遗留到后续的工作，例如PQ中进行确认，可以不作为本项测试否决项，但这些项目将遗留到OQ的遗留清单中，然后在后续的工作中进行确认。

And some issues which are required to be closed upon successful test execution as part of OQ. In that case, the issues should be closed after these tests are completed.  
某些遗留项目需要在成功完成OQ的某些测试之后才能被关闭，那么就等这些测试完成之后再来关闭该遗留项目。

**IQ Punch List Closeout Qualification  
IQ遗留清单关闭确认**

|  |  |
| --- | --- |
| The issues identified during IQ and which should be verified during OQ had been appropriately addressed as per the resolution listed next to each issue.在IQ活动中确定的需要在OQ阶段进行确认的遗留项目已经按照每一遗留项目旁边的应对措施进行了解决。 | Yes ( ) No ( ) |
| Attach the copy of Punch List and the support attachments to this document and record the attachment number. 将IQ遗留清单复印件及支持性附件附到本文件后，并记录附件编号。  Att. ID附件编号： | Yes ( ) No ( ) |

**Conclusion & Remarks结论和备注**

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **Access Control Test权限控制测试**

**Purpose目的**

This test is executed to indicate Authorized level of different user group and check the relevant operation activities of user group.  
确认用户组的不同权限并对不同用户组的操作进行检查。

**Acceptance Criteria可接受标准**

All actual test results are the same as the predetermined results of this test.  
所有实际测试结果与预期效果相符。

**Procedure程序**

Execute the operations as shown in the following tables and Inspect visually. Record the actual results.  
根据如下表格执行操作，目测检查。记录实际结果。

**Access Control Test  
权限控制测试**

|  |  |  |
| --- | --- | --- |
| User 用户 | Access Level 权限等级 | Actual Result 实际结果 |
| Administrator group  管理员组 | Level 1 1级权限 | Yes ( )No ( ) |
| Technologist group 工艺员组 | Level 2 2级权限 | Yes ( )No ( ) |
| Operator group 操作员组 | Level 3 3级权限 | Yes ( )No ( ) |
| steward group  维护员组 | Level 4 4级权限 | Yes ( )No ( ) |

| **team**  **项目** | | **Operation description**  **操作描述** | **Steward**  **维护员** | **Operator 操作员** | **Technologist**  **工艺员** | **Administrator 管理员** | **Yes/No**  **是否符合要求** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Function menu  功能菜单 | | User login  用户登录 | Yes是 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| User logged off  用户注销 | Yes是 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| User management  用户管理 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| Log out  退出系统 | Yes是 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| Operating functions  操作功能 | | Sample query  样本查询 | No否 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| Samples of the new  样本新建 | No否 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| Storage batches  存储批次 | No否 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| Retrieve the batch  取回批次 | No否 | Yes是 | Yes是 | Yes是 | Yes ( ) No ( ) |
| System data  系统数据 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| Parameter Settings 参数设置 | | New parameter  新建参数 | Yes是 | No否 | No否 | No否 | Yes ( ) No ( ) |
| Save the parameters  保存参数 | Yes是 | No否 | No否 | No否 | Yes ( ) No ( ) |
| Loading parameters  加载参数 | Yes是 | No否 | No否 | No否 | Yes ( ) No ( ) |
| Parameter settings  参数设置 | Yes是 | No否 | No否 | No否 | Yes ( ) No ( ) |
| Log 日志 | | Query log  查询日志 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| System data 系统数据 | Historical data 历史数据 | Query freezer box 查询冻存盒 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| Export  导出 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| Alarm data 报警数据 | Query freezer box 查询冻存盒 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| User management 用户管理 | | View the user.查看用户 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| User modification.  用户修改 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |
| New user  用户新建 | No否 | No否 | No否 | Yes是 | Yes ( ) No ( ) |

***Conclusion&Remarks结论和备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **Frozen storage box automated access test冻存盒自动化存取测试**

**Purpose目的**

Check the outbound and inbound process of the frozen storage box to confirm that it meets the requirements.  
检测冻存盒出库和入库流程，确认其符合要求。

**Acceptance Criteria可接受标准**

All actual test results are the same as the predetermined results of this test.  
所有实际测试结果与预期效果相符。

**Procedure程序**

Before opening the freezer box for extraction or storage, complete the initial setup of the device.  
开启冻存盒提取或存储前，完成设备初始化设定。

Turn on the device and complete the workspace cooling program.  
开启设备，完成工作区程序降温。

Automatic storage of devices.   
设备进行自动化存储。

Record the data in the table below.  
在下方表格里记录数据。

**Test result  
测试结果**

1. **Storage of frozen storage boxes  
   冻存盒入库**

| **Item 项目** | **Description 描述** | **Yes/No 是否符合要求** |
| --- | --- | --- |
| Transfer tank placement 中转罐放置 | After the transfer tank is opened automatically, remove the sealed top cover, place the transfer tank on the transfer tank, press the button of the door, the transfer tank will be closed automatically, and the transfer tank will be hoisted to the target position.  传递舱自动打开后，取下密封顶盖，将中转罐放置到传递舱上，按下舱门按钮，传递舱将自动关闭，并将中转罐顶升到目标位置。 | Yes ( ) No ( ) |
| Work chamber sorting operation 工作舱分拣作业 | Lifting device open  提盖装置打开 | Yes ( ) No ( ) |
| The target fan frame is rotated to the lower part of the lift cover. The lift cover and the target fan frame are raised to the target height synchronously  目标扇形架旋转至升降盖下方，升降盖与目标扇形架同步提升至目标高度 | Yes ( ) No ( ) |
| Extend the support plate to lift the sample plate frame, return the support plate to the designated position in the work cabin, complete the positioning of the sample plate frame, and lower the gate  托板伸出将样本板架托起，托板退回工作舱指定位置，完成样本板架定位，放下闸门 | Yes ( ) No ( ) |
| The robotic arm picks up the freezer boxes one by one and scans the code  机械臂依次挑取冻存盒，完成扫码 | Yes ( ) No ( ) |
| The robotic arm places the cryopreservation box to the target position of the sample plate rack  机械臂将冻存盒放置到样本板架目标位置 | Yes ( ) No ( ) |
| Freezer boxes are stored in liquid nitrogen tanks 冻存盒存储至液氮罐 | Fan frame and lift cover synchronously to target height  扇形架与升降盖同步提升至目标高度 | Yes ( ) No ( ) |
| Extend the pallet and put the sample tray back on the fan rack, then the pallet returns to the original position of the work compartment and lower the gate.  托板伸出将样本板架放回到扇形架上之后，托板退回工作舱原始位置，放下闸门。 | Yes ( ) No ( ) |
| Lower the fan frame to zero  降下扇形架至零点位置 | Yes ( ) No ( ) |
| Transfer tank removal  中转罐取出 | Close the lift device  关闭提盖装置 | Yes ( ) No ( ) |
| When waiting for the door button to flash, press the door button, the transfer tank will automatically descend, and the transfer door will automatically open. Then, remove the transfer tank, place the sealed top cover on the transfer cabin, and press the door button to close the transfer cabin.  等待舱门按钮闪烁时，按下舱门按钮，中转罐自动下降，传递舱门自动打开。然后，取下中转罐，再将密封顶盖放置到传递舱上，按下舱门按钮，关闭传递舱。 | Yes ( ) No ( ) |

1. **Frozen storage box out of storage  
   冻存盒出库**

| **Item 项目** | **Description 描述** | **Yes/No 是否符合要求** |
| --- | --- | --- |
| Transfer tank placement 中转罐放置 | After the transfer tank is automatically opened, take off the sealed top cover, place the transfer tank on the slide rail, press the button of the door, the transfer tank will automatically close, and lift the transfer tank to the target position.  传递舱自动打开后，取下密封顶盖，将中转罐放置到传递舱上，按下舱门按钮，传递舱将自动关闭，并将中转罐顶升到目标位置。 | Yes ( ) No ( ) |
| Work chamber sorting operation 工作舱分拣作业 | Lifting device open  提盖装置打开 | Yes ( ) No ( ) |
| The target fan frame is rotated to the lower part of the lift cover. The lift cover and the target fan frame are raised to the target height synchronously  目标扇形架旋转至升降盖下方，升降盖与目标扇形架同步提升至目标高度 | Yes ( ) No ( ) |
| Extend the support plate to lift the sample plate frame, return the support plate to the designated position in the work cabin, complete the positioning of the sample plate frame, and lower the gate  托板伸进将样本板架托起，托板退回工作舱指定位置，完成样本板架定位，放下闸门 | Yes ( ) No ( ) |
| The robotic arm picks up the freezer boxes one by one and scans the code  机械臂依次挑取冻存盒，完成扫码 | Yes ( ) No ( ) |
| The robotic arm places the freezing box at the target location of the transfer tank  机械臂将冻存盒放置中转罐目标位置 | Yes ( ) No ( ) |
| sample rack is returned to the liquid nitrogen tank 样本板架退回至液氮罐 | Fan frame and lift cover synchronously to target height  扇形架与升降盖同步提升至目标高度 | Yes ( ) No ( ) |
| Extend the pallet and put the sample tray back on the fan rack, then the pallet returns to the original position of the work compartment and lower the gate.  托板伸出将样本板架放回到扇形架上之后，托板退回工作舱原始位置，放下闸门。 | Yes ( ) No ( ) |
| Lower the fan frame to zero  降下扇形架至零点位置 | Yes ( ) No ( ) |
| Transfer tank removal  中转罐取出 | Close the lift device  关闭提盖装置 | Yes ( ) No ( ) |
| When waiting for the door button to flash, press the door button, the transfer tank will automatically descend, and the transfer door will automatically open. Then, remove the transfer tank, place the sealed top cover on the transfer cabin, and press the door button to close the transfer cabin.  等待舱门按钮闪烁时，按下舱门按钮，中转罐自动下降，传递舱门自动打开。然后，取下中转罐，再将密封顶盖放置到传递舱上，按下舱门按钮，关闭传递舱。 | Yes ( ) No ( ) |

***Conclusion&Remarks结论和备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **Access Sorting Operation Test 存取分拣作业测试**

***Purpose目的***

Check the operation control performance of the storage or Take out freezer box and confirm that it meets the requirements.  
检测存取冻存盒作业控制性能，确认其符合要求。

***Acceptance Criteria可接受标准***

All actual test results are the same as the predetermined results of this test.  
所有实际测试结果与预期效果相符。

***Procedure程序***

**Store the freezer box:  
存冻存盒：**

Log in to "Biobank Information Management System"  
登录“生物样本库信息化管理系统”，

Send the instruction of the freezer box to be stored to the storage device;  
将需存的冻存盒的指令发送给储存设备；

When the working chamber temperature reaches the set working temperature, the "confirm order" button will be displayed in the automatic mode interface. Click the "Confirm Order" button to open the transfer chamber, remove the lower cover, put the transfer tank with the frozen storage box into the transfer chamber, press the transfer hatch button, the storage device will run automatically, and the scan code will be correct. Finally, place the freezer box at the target location. Complete the storage operation.  
当工作舱温度达到设置好的工作温度后，在自动模式界面将显示“确认订单”按钮。点击“确认订单”按钮，传递舱门打开，取下下盖，将放有冻存盒的中转罐放入中转舱内，按下传递舱门按钮，存储设备将自动运行，并扫码无误，最后将冻存盒放置到目标位置。完成存储操作。

**Take** **freezer box out:  
取冻存盒：**

Log in to "Biobank Information Management System"  
登录“生物样本库信息化管理系统”；

Send the instruction to take the freezer box to the storage device;  
将需取冻存盒指令发送给储存设备；

When the working cabin temperature reaches the set working temperature, the "confirm order" button will be displayed in the automatic mode interface. Click the "Confirm Order" button, the storage device will automatically run, take out the target cryo-storage box, put it into the transfer tank, and then the transfer compartment door will automatically open, take out the transfer tank, put the lower cover back into the transfer compartment, press the transfer compartment door Button. Complete the operation of taking the freezer box.  
当工作舱温度达到设置好的工作温度后，在自动模式界面将显示“确认订单”按钮。点击“确认订单”按钮，存储设备将自动运行，取出目标冻存盒，将其放入中转罐，然后传递舱门自动打开，取出中转罐，将下盖放回传递舱，按下传递舱门按钮。完成取冻存盒操作。

**Test result  
测试结果**

|  |  |  |  |
| --- | --- | --- | --- |
| **Storage stage存储阶段** | | | |
| **Test sample**  **测试冻存盒** | **Whether the robotic arm sorting operation is completed机械臂分拣作业是否完成** | **Sweep the code completion**  **扫码是否完成** | **Sample plate rack to place target sector**  **样本板架是否放置目标扇区** |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Retrieve stage取回阶段** | | | |
| **Test sample**  **测试冻存盒** | **Sample tray remove target sector**  **样本板架是否取出目标扇区** | **Sweep the code completion**  **扫码是否完成** | **Whether the robotic arm sorting operation is completed**  **机械臂分拣作业是否完成** |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |
|  | Yes ( )  No ( ) | Yes ( )  No ( ) | Yes ( )  No ( ) |

***Conclusion & Remarks结论和备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

## **Alarm test报警测试**

**Purpose目的**

Verify key alarm will be activated properly and can be reset properly.  
确认关键报警能被正确触发和复位。

**Acceptance Criteria可接受标准**

Alarms are correctly generated, expected results and action due to alarm triggering is as per design.  
正确生成报警，由于报警触发而产生的预期结果和行动符合设计要求。

**Procedure程序**

The alarm tests are performed in operational mode.  
报警测试要在正常操作模式下进行。

For critical alarm, generate an alarm condition using one of the following:  
对关键报警，使用下面所列的方法之一来产生报警：

* Modifying the alarm threshold.  
  制造报警的极限。
* Using a proper signal generator.  
  使用适当的信号发生器。
* Disconnecting the device (sensor, instrument).  
  断开装置（传感器、仪表）。
* Disconnecting or shorting the signal cable (digital signals only).  
  断开或短接信号线（仅对数字信号）。
* Simulating “real condition”  
  在“真实的条件下”模拟。

Make sure that all the alarms work properly.  
确认报警功能正常。

Attach the alarm list to this test.  
附上检查过的报警清单作为此项测试的附件。

**Note/注:**

No alarm shall be trigged in a way that could damage the equipment.  
不能以有可能损坏设备的方式触发报警。

**Alarm Test  
报警测试**

| **No.**  **编号** | **Message**  **信息** | **Operation**  **操作** | **Expected Result**  **预期结果** | **Actual Result**  **实际结果** |
| --- | --- | --- | --- | --- |
| 1 | Warning-001: The right glove is not closed.  Warning-001：右手套未关闭。 | Open the right hand sleeve.  打开右手套板。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 2 | Warning-002: The left glove is not closed.  Warning-002：左手套未关闭。 | Open the left hand sleeve.  打开左手套板。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 3 | Warning-003: Dew point too high, dehumidification program started.  Warning-003：露点过高，程序已启动除湿。 | Open the opening of the glove to make the dew point in the cabin higher than -30℃.  打开手套口，使舱内露点高于-30℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 4 | Warning-005: Code not in batch or in wrong place.  Warning-005：码不在批次内或位置有误。 | Start a process, then replace a freezer box, and sort it.  启动一个流程，再替换一个冻存盒，并对其进行分拣工作。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 5 | Warning-006: Abnormal dew point.  Warning-006：露点异常。 | After the start a workflow, refrigeration, wear gloves to tank vapor through gloves into the work chamber, and form a white mist, causing the dew point to be higher than -40℃.  启动一个工作流程，制冷结束后，穿戴手套使水蒸气通过手套进入工作舱，并形成白雾，导致露点高于-40℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 6 | Warning-007: Abnormal supply of refrigerated liquid nitrogen in the working module.  Warning-007：工作舱制冷液氮补给异常。 | Close the manual valve of the self-pressurized liquid nitrogen tank and start a wokflow.  关闭自增压液氮罐手动阀，启动一个工作流程。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 7 | Warning-008: Storage tank liquid nitrogen level is too low.  Warning-008：储存罐液氮液位过低。 | The temperature probe of liquid nitrogen tank is higher than -188℃.  液氮罐高液位温度探头数据高于-188℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 8 | Warning-009: Storage tank liquid nitrogen level too high.  Warning-009：储存罐液氮液位过高。 | The temperature probe of liquid nitrogen tank is below -195℃.  液氮罐高液位温度探头数据低于-195℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 9 | Warning-010: The storage tank temperature is higher than -150℃, please check.  Warning-010：存储罐温度高于-150℃，请检查。 | The temperature probe data of liquid nitrogen tank sample is higher than -150℃.  液氮罐样本温度探头数据高于-150℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 10 | Warning-011: Abnormal automatic dehumidification.  Warning-011：自动除湿异常。 | Open the opening of the glove to make the dew point in the cabin higher than -25℃.  打开手套口，使舱内露点高于-25℃。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 11 | Warning-012: Scan failed, possibly because the code was unreadable.  Warning-012：扫码失败，可能原因：码不可读。 | Start a process and cover the QR code of the freezer box  启动一个流程，并将冻存盒二维码遮挡起来。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 12 | Warning-013: Abnormal supply of refrigerated liquid nitrogen in the working chamber.  Warning-013：工作舱制冷液氮补给异常。 | Start a working process. After the sorting work is officially started, close the manual valve of the self-pressurized liquid nitrogen tank, wait for the front compartment temperature to be higher than -125℃, and the refrigeration starts  启动一个工作流程，待正式开始分拣工作后，关闭自增压液氮罐手动阀，等待前舱温度高于-125℃，制冷启动。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 13 | Warning-014: Please go back to the origin.  Warning-014：请回原点。 | Power to restart.  断电重启。 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 14 | Error-001: Supply failure of refrigerated liquid nitrogen in the working chamber.  Error-001：工作舱制冷液氮补给故障。 | Close the manual valve of the self-pressurized liquid nitrogen tank and start a workflow.  关闭自增压液氮罐手动阀，启动一个工作流程。 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 15 | Error-005: Please place the transit tank and close the transfer cabin in time.  Error-005：请放置中转罐并及时关闭传递舱。 | Start a workflow, after confirming the order, open the transfer cabin and do not place the transit tank for more than 2 minutes.  启动一个流程，确认订单后，传递舱打开，超过2min不要放置中转罐。 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 16 | Error-006: Please take the transit tank and place the cover, and close the transfer cabin in time.  Error-006：请取走中转罐并放置盖，及时关闭传递舱。 | After the completion of the workflow, open the transfer cabin and do not close the transfer cabin after 2 minutes; or do not take the transit tank to close the transfer cabin.  流程结束后，打开传递舱，超过2min不要关闭传递舱；或不取走中转罐关闭传递舱 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 17 | Error-010: The upper cover device of the transfer cabin is stuck.  Error-010：传递舱上盖装置卡滞。 | Open and close the upper cover of the transfer cabin, and manually intervene to prevent it from falling.  将传递舱上盖打开再关闭，关闭时人工干预不使其落下。 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 18 | Error-015: Insufficient liquid nitrogen in storage tank.  Error-015：存储罐液氮不足。 | The low level temperature probe data of liquid nitrogen tank is higher than -195℃.  液氮罐低液位温度探头数据高于-195℃。 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 19 | Error-016: The temperature of storage tank is higher than -140℃, please check.  Error-016：存储罐温度高于-140℃，请检查。 | The temperature probe data of liquid nitrogen tank sample is higher than -140℃.  液氮罐样本温度探头数据高于-140℃。 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 21 | Warning-015 communication timeout  Warning-015通讯超时。 | Disconnect the BIS server network  断开BIS服务器网络 | The yellow light is on.  黄色指示灯亮。 | Yes( )  No( ) |
| 22 | Error-002: the straw z-axis touches or exceeds the limit  Error-002：吸盒轴触碰或超限 | Z axis touches or exceeds the stroke, alarm  Z轴触碰或超出行程，报警 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 24 | Error-004: The discharge box's Z-axis touches or exceeds the limit  Error-004：放盒轴触碰或超限 | Alarm when z-axis touches or exceeds the stroke  z轴触碰或超出行程，报警 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 25 | Error-007: The travel limit of the transfer cabin is exceeded  Error-007：传递舱行程超限 | Transfer cabin is out of itinerary  传递舱超出行程 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 26 | Error-008: Lift motor fault, please check: K05, motor wiring, lift stroke limited  Error-008：举升电机故障，请检查：K05、电机接线，举升行程受限 | Turn off the lifting motor and trigger operation  关闭举升电机，触发运行 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 27 | Error-009: Lift motor fault, please check: K06, motor wiring, descent stroke limited  Error-009：举升电机故障，请检查：K06、电机接线，下降行程受限 | Turn off the lifting motor and trigger operation  关闭举升电机，触发运行 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 28 | Error-011: The lifting stroke of the sector frame exceeds the limit  Error-011：扇形架升降行程超限 | Move the sector frame out of the stroke  将扇形架移动到行程外 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 29 | Error-012: Sector frame lifting stuck  Error-012：扇形架升降卡滞 | Turn off the fan-shaped frame lifting motor to trigger the movement  关闭扇形架提升电机，触发运动 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 30 | Error-013: The travel limit of the supporting plate inlet and outlet device is exceeded  Error-013：托板进出装置行程超限 | Move the pallet motor out of the stroke  将托板电机移动到行程外 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 31 | Error-014: The support plate inlet and outlet device is stuck  Error-014：托板进出装置卡滞 | Turn off the pallet motor and trigger the movement  关闭托板电机，触发运动 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 32 | Error-017：The Z-axis of the take box touches or exceeds the limit  Error-017：取盒Z轴触碰或超限 | z-axis touches or exceeds the stroke  z轴触碰或超出行程 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 33 | Error-018: The Z axis of the box is touching or exceeding the limit  Error-018：放盒Z轴触碰或超限 | z-axis touches or exceeds the stroke  z轴触碰或超出行程 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |
| 34 | Error-019: Z axis touches or exceeds the limit  Error-019：Z轴触碰或超限 | z-axis touches or exceeds the stroke  z轴触碰或超出行程 | The red light is on and the buzzer is ringing.  红色指示灯亮，蜂鸣器响。 | Yes( )  No( ) |

***Conclusion&Remarks结论和备注***

|  |  |
| --- | --- |
| Conclusion 结论 | |
| Remark备注： | |
| Conformity 符合性 | |
| Yes是 ( ) | No否 ( ) Deviation ID偏差编号\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Executed by / Date: 执行人/日期 |  |
| Reviewed by/ Date:  审核人/日期 |  |

1. Deviation Handling偏差处理

If the qualification result is not conformity with acceptance criteria, it shall fill in deviation record and determine the comments. If there are many deviation records, it should mark number in the deviation forms.  
如果确认结果与验收标准不符，应当填写偏差记录，明确处理意见，如果有多份偏差记录，则在偏差表上必须填好编号。

An independent ID is necessary for each deviation. Numbering for deviation shall be as per: D + section number-sequence number, such as the D10.1-01, means the first deviation of 10.1 section.  
每个偏差需要一个独立的编号。编号原则为：D+章节编号-顺序号，例如D10.1-01，代表10.1章节的第一个偏差。

Collect all found deviations during the OQ and record.  
收集OQ中发生的所有偏差并记录。

For all the found deviations during OQ, Tofflon need to provide solutions to close these deviations and the customer has responsible for reviewing and approving the solutions.  
OQ中发现的偏差，东富龙医疗装备需提出解决方法，由客户审核、批准解决方案。

Use copy of deviation record if necessary.  
如有需要可复印偏差记录。

**Deviation List  
偏差清单**

**(Page of )**

| Deviation ID  偏差编号 | Deviation Description  偏差描述 | Deviation Correction  偏差整改 | Other Description  其他说明 | Attachments  附件 | Conclusion  结论 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
| Executed by /Date  执行人/日期 | |  | | | |
| Reviewed by /Date  审核人/日期 | |  | | | |

1. Change Handling变更处理

Any change for this protocol, it shall fill in change report and determine the comments.  
如果需要对本文件变更，应填写变更报告，明确处理意见。

An independent ID is necessary for each Changing. Numbering for Changing shall be as per: C + section number-sequence number, such as the C10.1-01, means the first changing of 10.1 section.  
每个变更需要一个独立的编号。编号原则为：C+章节编号-顺序号，例如C10.1-01，代表10.1章节的第一个变更。

Collect all found changes during the OQ and record.  
收集OQ中发生的所有变更并记录。

For all the found changes during OQ, Tofflon need to provide solutions to close these deviations and the customer has responsible for reviewing and approving the solutions.  
OQ中发现的变更，东富龙医疗装备需提出解决方法，由客户审核、批准解决方案。

Use copy of Change report if necessary.  
如有需要可复印变更报告。

**Change List  
变更清单**

**(Page of )**

| Change ID  变更编号 | Change Description  变更描述 | Change Correction  变更整改 | Other Description  其他说明 | Attachments  附件 | Conclusion  结论 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
| Executed by /Date 执行人/日期 | |  | | | |
| Reviewed by /Date 审核人/日期 | |  | | | |

1. Punch List 遗留清单

If there are any issues which need to be verified in following work and a punch list shall be drafted as per the requirements.   
如果尚有未决事项需要遗留到后续工作，则需要按照遗留项目要求起草遗留工作清单。

An independent ID is necessary for each Punch. Numbering for Punch shall be as per: P + section number-sequence number, such as the P10.1-01, means the first punch of 10.1 section.  
每个遗留项目需要一个独立的编号。编号原则为：P+章节编号-顺序号，例如P10.1-01，代表10.1章节的第一个遗留项目。

Collect all found punch during the OQ and record.  
收集OQ中发生的所有遗留项并记录。

**Punch List  
遗留清单**

**(Page of )**

| Punch ID  遗留项目编号 | Punch Description  遗留问题描述 | Punch Correction  遗留问题整改 | Other Description  其他说明 | Attachments  附件 | Conclusion  结论 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
|  |  |  |  | N/A ( )  Att. ID: **\_\_\_\_\_\_\_\_** | Yes ( )  No ( ) |
| Executed by /Date 执行人/日期 | |  | | | |
| Reviewed by /Date 审核人/日期 | |  | | | |

1. Attachment List附件清单

Record all the documents attached to this report and record.  
记录所有附在本报告中的文件并记录。

An independent ID is necessary for each attachment. Numbering for attachment shall be as per: A + section number-sequence number, such as the A10.1-01, means the first attachment of 10.1 section.  
每个附件需要一个独立的编号。编号原则为：A+章节编号-顺序号，例如A10.1-01，代表10.1章节的第一个附件。

The executor shall sign name and date on the first page and the last page, and indicate the page number on each page as per X/X, such as the 1/10, means the first page of a ten page attachment.  
执行人员应在附件的首末页签字，并在每页上注明页码：X/X，例如：1/10，代表一个共有10页的附件的第一页。

**Attachments List  
附件清单**

**(Page of )**

|  |  |  |
| --- | --- | --- |
| Attachment ID 附件编号 | Attachment Description  附件描述 | Pages  页数 |
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1. OQ Summary OQ总结

## **Test Result Summary 测试结果汇总**

| Test No. 测试编号 | Test Name 测试名称 | Conclusion  结论 | Deviation ID  偏差编号 | Punch List ID  遗留项目编号 |
| --- | --- | --- | --- | --- |
|  | Prerequisites  先决条件 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | Test instruments calibration Qualification  测试用仪器仪表校准确认 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | SOP Qualification  SOP确认 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | IQ Punch List Closeout Qualification  IQ遗留清单关闭确认 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | Access control test  权限控制测试 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | Sample automated access testing  样本自动化存取测试 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | Access Sorting Operation Test  存取分拣作业测试 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
|  | Alarm test  报警测试 | Yes ( ) No ( ) | N/A ( )  Dev. ID: **\_\_\_\_\_\_\_\_** | N/A ( )  PL. ID: **\_\_\_\_\_\_\_\_** |
| Executed by /Date 执行人/日期 | |  | | |
| Reviewed by /Date 审核人/日期 | |  | | |

## **OQ Conclusion OQ结论**

Review the test result and data, and give a final conclusion for OQ of Automatic liquid nitrogen storage system.  
对测试结果和数据进行审核，得出全自动液氮存储系统运行确认的最终结论。

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**OQ Review and Approval  
OQ 审核与批准**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Department or Company** **部门或公司** | **Result** **结果** | **Signature/Date** **签名/日期** |
| **CHECKED BY:**  **(by Supplier)**  **核查（供应商）** |  | Yes ( ) No ( ) |  |
| **CHECKED BY:**  **(by Supplier)**  **核查（供应商）** |  | Yes ( ) No ( ) |  |
| **REVIEWED BY:**  **(by Customer)**  **审核（用户）** |  | Yes ( ) No ( ) |  |
| **REVIEWED BY:**  **(by Customer)**  **审核（用户）** |  | Yes ( ) No ( ) |  |
| **REVIEWED BY:**  **(by Customer)**  **审核（用户）** |  | Yes ( ) No ( ) |  |
| **APPROVED BY:**  **(by Customer)**  **批准（用户）** |  | Yes ( ) No ( ) |  |