1.质量标准Quality Standard

| 序号  No | 项目  Item | 接受标准  Acceptance Criteria | 检测器具和设备  Test Apparatus and Equipment | 检测方法  Test Method | 严重度  Severity | 抽样方案  Sample Plan |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | 材质 | 橡胶 | / | 核实供方提供的随批资料 | B | 全检 |
| 2 | 外观 | 干净无污渍 | / | 目视 | B | 全检 |
| 3 | 尺寸 | 外径7±0.5mm，线径±0.2mm | 视觉设备 | 根据尺寸特点及量具选择定义检测方法 | B | 全检 |

2. 单证资料Certification Document:

1. 出厂检验报告（批批提供），应包括以下内容：
2. 物料名称/规格、生产批量、生产批号、材质等信息。
3. 应列出质量标准中需要进行出厂检的检验项目及检验结果，且结果合格。
4. 其他双方协商必要的项目；
5. 出厂检验报告应经供方确认。

注：出厂检验报告应是物料供应商直接提供的随批资料。

1） The factory inspection report (provided in batches), should include the followings:

a) Material name/specification, production batch, batch number, material and other information.

b) The inspection items and inspection results that need to be inspected in the quality standard shall be listed, and the results shall be qualified.

c) Necessary items negotiated by both;

d) The factory inspection report should be confirmed by the supplier.

1. 材质证明文件（批批提供），应包括以下内容；
2. 材质名称/规格/牌号，生产批号等信息；
3. 质量标准要求的材质成分及其他性能信息；

注：材质证明文件一般是物料供应商生产本物料时所使用的原材料的相关资料。

2) Material certification documents (provided in batches), should include the followings;

a) Material name/specification/grade, batch number and other information;

b) Material composition and other performance information required by quality standards;

3.图纸号Drawing No. :

AAA-10100045-10

4. 批的定义Lot Definition :

生产批：在一段时间内，同一生产工艺条件下连续神产出的具有同一性质和质量的产品确定的数量。

[production](javascript:;) Lot: A defined quantity of a product with the same performance and quality produced continuously over a period of time under the same process conditions.

5.生产场地和环境要求Manufacture Place and Environment Requirements:

无

6. 包装&运输要求Packaging &Shipping Requirements:

普通物料：

供应商应提供合适的包装防护措施，确保产品在运输过程中不发生损坏；在包装外部可见的地方应粘贴标签，显示货物名称、批号、数量等信息。

For ordinary materials: The supplier shall provide suitable package to ensure that the product is not damaged during transportation; a label shall be affixed visibly on the outside of the package to display the name, batch number, quantity etc...

洁净物料：

供应商应提供合适的包装防护措施，确保产品在运输过程中不发生损坏；在包装外部可见的地方应粘贴标签，显示货物名称、批号、数量等信息；内层包装采用双层密封包装（于净化车间完成）；外层包装采用的包装用料不得在运输存贮过程中影响产品质量；运输过程中包装应防潮、防晒、防雨淋；防破损、防变形、防污染。

The supplier shall provide appropriate packaging protection measures to ensure that the product is not damaged during transportation; labels should be affixed visibly outside the package, showing information such as name, lot number, quantity, etc. The inner packaging shall be packed with double sealed package (completed in the purification workshop); the outer packaging materials shall not affect the quality of the product during transportation and storage; the packaging shall be moisture-proof, sun-proof, and rain-proof during the transportation process and can prevent damage, deformation, and pollution.

7.售后服务After Service:

当有重要原材料变化、设计变更或产品有严重质量问题时通知上海神玑医疗科技股份有限公司。

Shanghai ShenJi Medical Technology Corporation Limited is notificated when there are important changes in raw materials, design changes or serious quality problems of products.

8.备注Remark:

无

9.签字 Signature:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 编制人Compiled by |  | 标准化Controlled by |  | 质量工程师或质量经理审核  Review by QA Engineer or QA Manager |  | 项目经理批准  Approved by PM |  |
| 日 期Date |  | 日 期Date |  | 日 期  Date |  | 日 期  Date |  |

10.供方确认Confirmed by Supplier:

|  |  |  |  |
| --- | --- | --- | --- |
| 供应商名称  Supplier name | 部门  Department | 职务  Duty | 确认人/确认日期  Confirmed by/Date |
|  |  |  |  |

适用时应获得供方的签字，并注明日期。应写明供方确认的条款一旦发生变化时应通知对方，重新签订质量标准。

11.文件变更历史Version History:

**文件变更历史**

|  |  |  |  |
| --- | --- | --- | --- |
| 版本  Version | 编写日期  Compiled Date | 编制人  [Editor](javascript:;) | 变更内容  Change content |
| A | 2022-02-14 | 熊科 | 建立新文件。 |