

## 移液管最终质量检查表 Serological pipettes Quality Final Check List

|                          |              |                         |            |
|--------------------------|--------------|-------------------------|------------|
| 目录号<br>Catalog Number    | GSP020010    | 规格<br>Specifications    | 10mL       |
| 批号<br>Lot Number         | 221116-070-A | 有效期<br>Expiration Date  | 2025-11-16 |
| 生产日期<br>Manufacture Date | 2022-11-16   | 检验日期<br>Inspection Date | 2022-11-19 |

## 检验项目及结果 Inspection Item and Result

| 检验项目及标准<br>Inspection Item and Standard |                                                                                                                                                                                                                                                  | 接收水平<br>Acceptance Level                                                                                          |                    |               | 检验结果<br>Inspection Result                                         |                 |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|--------------------|---------------|-------------------------------------------------------------------|-----------------|
|                                         |                                                                                                                                                                                                                                                  | 检验水平<br>Quality Level                                                                                             | 样品数<br>Sample Size | 收: 退<br>Ac:Re | 结果<br>Result                                                      | 判断<br>Judgement |
| 外观<br>Appearance                        | 产品规格、色环颜色正确, 管体透明无杂色、晶点、破裂、明显重影; 无堵嘴、无严重歪头、歪嘴、刮花磨损等; 包装完整,<br>With right specifications and color ring, transparent body. Without crystal point, crack, obvious double shadow. No plugging, deformation, scratches etc. With complete packaging. | 依据标准: GB/T 2828.1-2012<br>Standard: GB/T2828.1-2012<br>抽样水平: Level II, AQL 1.5<br>Sample Level: Level II, AQL 1.5 |                    |               | 符合/Meet criteria                                                  | 合格/OK           |
| 性能<br>Function                          | 容量允差: $\pm 2\%$ Capacity: within $\pm 2\%$                                                                                                                                                                                                       | C=0                                                                                                               | 10                 | 0: 1          | 符合/Meet criteria                                                  | 合格/OK           |
|                                         | 管体的密封性 Sealing property                                                                                                                                                                                                                          | C=0                                                                                                               | 10                 | 0: 1          | 符合/Meet criteria                                                  | 合格/OK           |
|                                         | 油墨牢固度 Ink Fastness                                                                                                                                                                                                                               | C=0                                                                                                               | 10                 | 0: 1          | 符合/Meet criteria                                                  | 合格/OK           |
|                                         | 管头超声强度<br>Ultrasonic intensity of top end                                                                                                                                                                                                        | C=0                                                                                                               | 10                 | 0: 1          | 符合/Meet criteria                                                  | 合格/OK           |
|                                         | 流出时间 Outflow                                                                                                                                                                                                                                     | C=0                                                                                                               | 10                 | 0: 1          | 符合/Meet criteria                                                  | 合格/OK           |
| 生物性能<br>Biological Performance          | 无菌<br>Sterilized(SAL= $10^{-6}$ )                                                                                                                                                                                                                | C=0                                                                                                               | 3                  | 0: 1          | 样品 Samples: - - -<br>阳性对照 Positive: + + +<br>阴性对照 Negative: - - - | 合格/OK           |
|                                         | 热原 $\leq 0.5\text{EU/mL}$<br>Non-Pyrogenic ( $\leq 0.5\text{EU/mL}$ )                                                                                                                                                                            | C=0                                                                                                               | 3                  | 0: 1          | 样品 Samples: - - -<br>阳性对照 Positive: + + +<br>阴性对照 Negative: - - - | 合格/OK           |
|                                         | 细胞毒性<br>Cytotoxicity                                                                                                                                                                                                                             | C=0                                                                                                               | 3                  | 0: 1          | 样品 Samples: - - -<br>阳性对照 Positive: + + +<br>阴性对照 Negative: - - - | 合格/OK           |
|                                         | 无酶<br>DNase & RNase Free                                                                                                                                                                                                                         | C=0                                                                                                               | 3                  | 0: 1          | 样品 Samples: - - -<br>阳性对照 Positive: + + +<br>阴性对照 Negative: - - - | 合格/OK           |
| 最终判断 Final Judgement                    |                                                                                                                                                                                                                                                  | 接收 Accept                                                                                                         |                    |               | 拒收 Reject                                                         |                 |

签名 Signature

检验 Inspected by

审核 Approved by

张 卫 强

质量部

马 菊 菊