

常规针最终检测报告  
Disposable Sterile Lancet Inspection Report

## 检验信息/Inspection Information:

|                                    |                                                                                           |                      |                                     |                           |                                   |                                 |                        |                 |
|------------------------------------|-------------------------------------------------------------------------------------------|----------------------|-------------------------------------|---------------------------|-----------------------------------|---------------------------------|------------------------|-----------------|
| 产品名称<br>Product Name               | 一次性使用末梢采血针<br>Disposable Sterile Lancets                                                  | 产品编码<br>Product Code | C.P.01K.28.NX2-50H01                |                           | 订单号/<br>数量<br>P/O No/<br>Qty(PCS) | HHT24101815<br>/<br>50400000PCS | 出货数量<br>Quantity (PCS) | 34560000<br>PCS |
| 产品规格/型号<br>Spec/Model #            |                                                                                           | 28G/1                | 批号<br>Lot No                        | 2410123                   | 有效期<br>Exp. Date                  | 2029-11-21                      |                        |                 |
| 客户物料编码<br>Customer Material Coding |                                                                                           | 40200042             | 客户物料名称<br>Name of customer material | 三诺专供50支盒装采血针 50支/盒，一箱装60盒 |                                   |                                 |                        |                 |
| 检验依据<br>Inspection Reference       | 《一次性使用末梢采血针检验规范》HH-QD-OQC-01<br>《Inspection Specification for Disposable Sterile Lancets》 |                      |                                     |                           |                                   | 生产日期<br>Mfg.Date                | 2024-11-22             |                 |

## 检验内容/Inspection Items:

| 检验项目<br>Inspection Items | 检验要求<br>Criteria                       | 测试工具<br>Inspection Tool                                           | 工具<br>编号<br>Tool No | 质量水平<br>Quality Level | AQL | 抽样数<br>Qty Sampled | Ac/Re | 判定<br>结果<br>Result |
|--------------------------|----------------------------------------|-------------------------------------------------------------------|---------------------|-----------------------|-----|--------------------|-------|--------------------|
| 参数检测<br>Parameter        | 针的直径<br>Diameter of needle             | 游标卡尺/千分尺/影像测试仪<br>Vernier Caliper/<br>Micrometer/<br>Image tester | HJA024/<br>HJB003   | S-2                   | 1.0 | 13                 | 0 1   | 合格<br>Qualified    |
|                          | 总长度<br>Total Length                    |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
|                          | 塑柄长度<br>Length of plastic handle       |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
|                          | 塑柄宽度<br>Width of plastic handle        |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
|                          | 塑柄厚度<br>Thickness of plastic handle    |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
|                          | 针尖露出长度<br>Length of exposed needle     |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
|                          | 针尖裸露长度<br>Exposed length of needle tip |                                                                   |                     |                       |     |                    |       | 合格<br>Qualified    |
| 外观检测<br>Appearance       | 产品外观<br>Product Appearance             | 目测<br>Visual Inspection                                           | NA                  | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified    |
|                          |                                        | 目测<br>Visual Inspection                                           | NA                  | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified    |
|                          | 产品外观<br>Product Appearance             | 目测<br>Visual Inspection                                           | NA                  | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified    |
|                          |                                        | 目测<br>Visual Inspection                                           | NA                  | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified    |



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|                                                                                                           |                                                   |                                                                                                                                                                                                                                                                                                                                                          |                                            |                       |     |          |          |   |            |                 |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-----------------------|-----|----------|----------|---|------------|-----------------|
| 检验信息/Inspection Information                                                                               |                                                   |                                                                                                                                                                                                                                                                                                                                                          |                                            |                       |     |          |          |   |            |                 |
| 外观检测<br>Appearance                                                                                        | 针尖检验<br>Needle Tip Inspection                     | No burr, tip, tip (barb), white spot (bald tip), rust, oil and other defects.after screwing the cap, there is no obvious sticky coating material and serious burr etc<br>针尖不得有毛刺,翘尖,碰尖 (倒钩),白点 (秃尖),锈迹,油污等缺陷,拧帽后无明显粘包料和严重毛刺                                                                                                                              | 目测/显微镜<br>Visual Inspection/<br>Microscope | HJD003                | S-3 | 0.4      | 32       | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 清洁度<br>Cleanliness                                | Clean and free of dust, grease and dirt<br>清洁、无灰尘、油污、脏污                                                                                                                                                                                                                                                                                                  | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125      | 3 | 4          | 合格<br>Qualified |
| 性能检测<br>Performance                                                                                       | 针体与针柄牢固度<br>Firmness of needle and plastic handle | 11:16G-38G≥5N<br>其余型号: 16G-30G≥22N,31-38G≥5N                                                                                                                                                                                                                                                                                                             | 牢固度测试仪<br>Strength Tester                  | HJE065                | S-2 | 1.0      | 13       | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 穿刺力<br>Puncture Force                             | 26G-38G≤1N;20G-25G≤1.5N;18G-19G≤2N;<br>16G<4N                                                                                                                                                                                                                                                                                                            | 穿刺力测试仪<br>Puncture Force Teter             | HJE017                | S-2 | 1.0      | 13       | 0 | 1          | 合格<br>Qualified |
| 耐腐蚀性<br>Corrosion Resistance                                                                              |                                                   | The corrosion resistance of the needle tip should reach grade b or above<br>针尖的耐腐蚀性能不低于b级要求                                                                                                                                                                                                                                                              | 目测<br>Visual Inspection                    | NA                    | S-4 | 0.65     | 125      | 2 | 3          | 合格<br>Qualified |
| 包装<br>Package                                                                                             | 产品信息<br>Product Info                              | Correct shipping mark, accessories, packing method, inkjet, labeling position and product<br>唛头,附件,包装方式,喷码,贴标位置,产品正确                                                                                                                                                                                                                                     | 目测<br>Visual Inspection                    | NA                    | S-2 | Ac0, Re1 | 13盒      | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 数量<br>Quantity                                    | Correct quantity<br>包装数量准确,无偏差                                                                                                                                                                                                                                                                                                                           | 数数/电子秤<br>Count/Electronic Balance         | HJF101                | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           | 封口/外观<br>Seal/Appearance                          | Clean and free of dust, grease and dirt<br>外观保持清洁等; 无灰尘,油污,脏污                                                                                                                                                                                                                                                                                            | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           |                                                   | No open paste, missing paste, dirty paste, no obvious cutting skew, color difference, forming defects, linear defects, spot defects, printing or coding defects, folds, damage, residual material, residual glue, overflow glue, burst edge, burst line, pressed products, etc<br>无开贴,漏贴,脏贴,无明显的裁切歪斜,色差,成型缺陷,线状缺陷,点状缺陷,印刷或喷码缺陷,褶皱,破损,残料,残胶,溢胶,爆边,爆线,压产品等 | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           |                                                   | No blood,hair,insect<br>无血渍,毛发,昆虫                                                                                                                                                                                                                                                                                                                        | 目测<br>Visual Inspection                    | NA                    | S-4 | Ac0, Rel | 125盒     | 0 | 1          | 合格<br>Qualified |
| 灭菌/Sterilization                                                                                          |                                                   | Check the certificate,and meet requirements, and the survival probability of microorganism is ≤1*10 <sup>-6</sup><br>核对辐照证明书满足要求,微生物存活概率≤1*10 <sup>-6</sup>                                                                                                                                                                                              | 目测<br>Visual Inspection                    | 核对结果/Check the result |     |          |          |   |            | 合格<br>Qualified |
| 原始数据见附表《常规针最终检测数据记录》/Detailed raw data refer to attached Inspection Result for Disposable Sterile Lancets |                                                   |                                                                                                                                                                                                                                                                                                                                                          |                                            |                       |     |          |          |   |            |                 |
| 检验结论/Inspection Conclusion:                                                                               |                                                   |                                                                                                                                                                                                                                                                                                                                                          | 合格/Qualified                               |                       |     |          |          |   |            |                 |
| 判定结果/Result                                                                                               |                                                   |                                                                                                                                                                                                                                                                                                                                                          | 合格/Qualified                               |                       |     |          |          |   |            |                 |
| 检验人员/Inspector:                                                                                           |                                                   |                                                                                                                                                                                                                                                                                                                                                          | 木子明                                        |                       |     |          | 日期/Date: |   | 2024-12-25 |                 |
| QC主管/QC Manager:                                                                                          |                                                   |                                                                                                                                                                                                                                                                                                                                                          | 张欣                                         |                       |     |          | 日期/Date: |   | 2024-12-25 |                 |



# 辐照证明书

CERTIFICATE OF IRRADIATION

证书编号: 202412010  
Certificate No.:

加工编号 2024121001  
Process Code No.:

天津爱邦辐射技术有限公司

TIANJIN ELPONT RADIATION TECHNOLOGY CO., LTD.

地址(Add): 天津市武清区泗村店镇功能开发区

Si Cun Dian function development zone, Wuqing, Tianjin, China

电话(TEL): +86 (0) 22 29429066

传真(FAX): +86 (0) 22 29429066

邮政编码: 301709

公司网址: <http://www.tjelpont.com>

| 顾客名称<br>Customer 天津华鸿科技股份有限公司 |                             |                         |                         |                    |
|-------------------------------|-----------------------------|-------------------------|-------------------------|--------------------|
| 产品名称<br>Article description   | 包装规格(厘米)<br>Carton Size(cm) | 产品批号<br>Article Lot No. | 数量(箱)<br>Carton Qty(cs) | 毛重(公斤)<br>G.W(kgs) |
| 一次性使用末梢采血针                    | 25.5*21.4*14.2              | 2410123                 | 11520                   | 18432              |

这批产品已经过电子射线辐射。

THE PRODUCTS HAVE BEEN IRRADIATED BY ELECTRON BEAM.

加工编号 2024121001  
Process Code No.

辐照结束的日期 2024-12-10  
Irradiation lot finish date

顾客要求最低平均吸收剂量: 25 kGy  
Minimum specified dose:

最低有效吸收剂量: 26.32 kGy  
Minimum inspection area

顾客要求最高平均吸收剂量: 50 kGy  
Maximum specified dose:

最高耐受吸收剂量: 42.85 kGy  
Maximum inspection area

检验员: 王丽娜  
Inspector:

审核: 朱玉辉  
Approved:

日期: 2024.12.10  
Date:

天津爱邦辐射技术有限公司  
TIANJIN ELPONT RADIATION TECHNOLOGY CO., LTD.

检验专用章

(本证明书的影印件与原件一致。The copy of this certificate is consistent with the original.)



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## Sterility Test Report

## 无菌试验报告

Test Date 实验日期: 2024.12.11

Report Date 报告日期: 2024.12.25

|                                                                                          |                                                                                                                                                                                                                          |                                                                       |                                                                                                                              |
|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Product Name<br>样品名称                                                                     | 一次性使用末梢采血针                                                                                                                                                                                                               | PO No.<br>订单号                                                         | HHT24101815                                                                                                                  |
| Certificate of<br>Irradiation No<br>辐照证明书<br>编号                                          | 202412010                                                                                                                                                                                                                | Inspection<br>Criteria<br>检验依据                                        | Pharmacopoeia of the<br>People's Republic of<br>China (2020) 中华人民共和国<br>药典 (2020 版)<br>GB/T 19973-2:2018<br>GB/T14233.2-2005 |
| Product Code<br>产品编码                                                                     | C. P. 01K. 28. NX2-50H01                                                                                                                                                                                                 | Lot No.<br>批号                                                         | 2410123                                                                                                                      |
| Cultivation time<br>of test product<br>供试品培养时间                                           | 14 天                                                                                                                                                                                                                     | Temperature<br>温 度                                                    | Bacteria 细菌: 32℃<br>Fungus 真菌: 23℃                                                                                           |
| Culture time of<br>positive control<br>and sedimentation<br>bacteria<br>阳性对照及沉降菌<br>培养时间 | 3 天                                                                                                                                                                                                                      | Temperature<br>温 度                                                    | 32℃                                                                                                                          |
| Incubator number<br>培养箱编号                                                                | HJE011                                                                                                                                                                                                                   | Incubator number<br>培养箱编号                                             | HJE048                                                                                                                       |
| Pipette number<br>移液枪编号                                                                  | HJE416                                                                                                                                                                                                                   | Number of<br>high-pressure<br>steam<br>sterilization pot<br>高压蒸汽灭菌锅编号 | HJE047                                                                                                                       |
| Name, batch number<br>and purpose of<br>medium 培养基名称<br>批号、用途                            | 1、Thioglycollate Medium (for bacteria testing) 硫乙醇酸盐培养基(用于细菌<br>检测): 230717<br>2、TSB (for fungus testing) 胰酪大豆胨液体培养基(用于真菌检测): 230529<br>3、TSA medium (Used for environmental monitoring) 胰酪大豆胨琼脂培养基(用<br>于环境监测): 2308192 |                                                                       |                                                                                                                              |
| Inoculation mode<br>接种方式                                                                 | Direct inoculation 直接接种法                                                                                                                                                                                                 |                                                                       |                                                                                                                              |

版本: E, 修改次数: 1



No. 编号: 24122501

III-QR-QD-LAB-WI-07-01

|                                                                                                                                                                                                              |  |                                                                                                         |                            |                            |                          |                       |                              |              |                |          |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------|----------------------------|----------------------------|--------------------------|-----------------------|------------------------------|--------------|----------------|----------|--|
| Sample size<br>抽样量                                                                                                                                                                                           |  | 60 件                                                                                                    |                            |                            |                          |                       |                              |              |                |          |  |
| Test Result<br>检 验 结 果                                                                                                                                                                                       |  |                                                                                                         |                            |                            |                          |                       |                              |              |                |          |  |
| Identification of<br>bacteria 鉴别菌                                                                                                                                                                            |  | aerobe、anaerobe 需氧菌、厌氧菌<br>30℃-35℃                                                                      |                            |                            |                          |                       | fungus、aerobe 真菌、需氧菌 20℃-25℃ |              |                |          |  |
| Group 组别                                                                                                                                                                                                     |  | sa<br>mp<br>le<br>样<br>品                                                                                | nog<br>ati<br>ve<br>阴<br>性 | pos<br>iti<br>ve<br>阳<br>性 | settling micro<br>be 沉降菌 |                       |                              | sample<br>样品 | negative<br>阴性 | 备 注 note |  |
|                                                                                                                                                                                                              |  |                                                                                                         |                            |                            | ves<br>sel<br>1皿<br>1    | ves<br>sel<br>2皿<br>2 | ves<br>sel<br>3皿<br>3        |              |                |          |  |
| Cultivate Period<br>培养时间                                                                                                                                                                                     |  | 3<br>d                                                                                                  | -                          | -                          | +                        | 0                     | 0                            | 0            | -              | -        |  |
|                                                                                                                                                                                                              |  | 5<br>d                                                                                                  | -                          | -                          |                          |                       |                              |              | -              | -        |  |
|                                                                                                                                                                                                              |  | 7<br>d                                                                                                  | -                          | -                          |                          |                       |                              |              | -              | -        |  |
|                                                                                                                                                                                                              |  | 1<br>d                                                                                                  | -                          | -                          |                          |                       |                              |              | -              | -        |  |
| Conclusion<br>检测结论                                                                                                                                                                                           |  | After testing, the sterility test results of this batch of products are<br>qualified<br>经检测本批产品无菌测试结果合格 |                            |                            |                          |                       |                              |              |                |          |  |
| 注 Note: “-”: negative 阴性 “+”: positive 阳性<br>negative pair care for “-”、Positive pair care for “+”、Sample set for “-”<br>settling microbe/vessel ≤ 1 qualified 阴性对照管为“-”、阳性对照管为“+”、样品组为“-”<br>沉降菌/皿 ≤ 1 即为合格 |  |                                                                                                         |                            |                            |                          |                       |                              |              |                |          |  |

Inspected by 检验人: 李斯睿

Verified by 复核人: 李斯睿

Approved by 批准人: 李斯睿

Date 日期: 2024-12-25

Date 日期: 2024-12-25

Date 日期: 2024.12.25



版本: E, 修改次数: 1


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|------------------------------------|-------------------------------------------------------------------------------------------|----------------------|-------------------------------------|---------|----------------------------------|---------------------------------|-------------------------------|-----------------|--|
| 检测信息/Inspection Information:       |                                                                                           |                      |                                     |         |                                  |                                 |                               |                 |  |
| 产品名称<br>Product Name               | 一次性使用末梢采血针<br>Disposable Sterile Lancets                                                  | 产品编码<br>Product Code | C.P.01K.28.NX2-50H01                |         | 订单号/<br>数量<br>PO No/<br>Qty(PCS) | HHT24101815<br>/<br>50400000PCS | 出货<br>数量<br>Quantity<br>(PCS) | 34560000<br>PCS |  |
| 产品规格/型号<br>Spec/Model #            | 28G/I                                                                                     |                      | 批号<br>Lot No                        | 2410123 |                                  | 有效期<br>Exp. Date                | 2029-11-21                    |                 |  |
| 客户物料编码<br>Customer Material Coding | 40200042                                                                                  |                      | 客户物料名称<br>Name of customer material |         | 三诺专供50支盒装采血针 50支/盒，一箱装60盒        |                                 |                               |                 |  |
| 检验依据<br>Inspection Reference       | 《一次性使用末梢采血针检验规范》HH-QD-OQC-01<br>《Inspection Specification for Disposable Sterile Lancets》 |                      |                                     |         |                                  | 生产日期<br>Mfg.Date                | 2024-11-22                    |                 |  |

## 检验内容/Inspection Items:

| 检验项目<br>Inspection Items |                                        | 检验要求<br>Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 测试工具<br>Inspection Tool                                       | 工具编号<br>Tool No   | 质量水平<br>Quality Level | AQL | 抽样数<br>Qty Sampled | Ac/Re | 判定结果<br>Result  |
|--------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------|-----------------------|-----|--------------------|-------|-----------------|
| 参数检测<br>Parameter        | 针的直径<br>Diameter of needle             | 与图纸一致<br>Meet with drawings<br>(HH00373/Rev.15)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 游标卡尺/千分尺/影像测试仪<br>Vernier Caliper/<br>Micrometer/Image tester | HJA024/<br>HJB003 | S-2                   | 1.0 | 13                 | 0 1   | 合格<br>Qualified |
|                          | 总长度<br>Total Length                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
|                          | 塑柄长度<br>Length of plastic handle       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
|                          | 塑柄宽度<br>Width of plastic handle        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
|                          | 塑柄厚度<br>Thickness of plastic handle    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
|                          | 针尖露出长度<br>Length of exposed needle     | 3.3±0.25mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
|                          | 针尖裸露长度<br>Exposed length of needle tip | 不低于0.5mm<br>No less than 0.5mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                               |                   |                       |     |                    |       | 合格<br>Qualified |
| 外观检测<br>Appearance       | 产品外观<br>Product Appearance             | The color is correct, consistent with the order requirements, and the color difference is in line with the sealing sample; the surface has no obvious color flow, shrinkage, flow marks, material flowers, deformation, insufficient mold, missing meat, strain, mold marks, bubbles, impurities, black spots, foreign bodies, no obvious scratches, raw edges, multiple materials, burrs, dislocation, not head, broken needles, etc.<br>颜色正确,与订单要求一致,色差符合封样;<br>表面无明显色流,缩水,流痕,料花,变形,不饱模,缺肉,拉伤,模具痕,气泡,杂质,黑点,异物,无明显的划痕,毛边,多料,毛刺,错位,不出头,碎针等 | 目测<br>Visual Inspection                                       | NA                | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified |
|                          | 产品外观<br>Product Appearance             | No defects such as empty needle, back stitch, double needle, protective cap tilted, no empty needle, double needle, bent needle                                                                                                                                                                                                                                                                                                                                                                                                            | 目测<br>Visual Inspection                                       | NA                | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified |
|                          |                                        | No fracture, rupture, damage, crack, scorch; No less pieces, mixing, etc.; 无断裂,破裂,损坏,裂纹,烧焦,无少件,混料等;                                                                                                                                                                                                                                                                                                                                                                                                                                        | 目测<br>Visual Inspection                                       | NA                | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified |
|                          |                                        | No blood, hair, insect 无血渍,毛发,昆虫                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 目测<br>Visual Inspection                                       | NA                | S-3                   | 0.4 | 32                 | 0 1   | 合格<br>Qualified |

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Version: E, Revision Times: 4

常规针最终检测报告  
Disposable Sterile Lancet Inspection Report

## 检验信息/Inspection Information:

| 检验信息/Inspection Information:                                                                              |                                                   |                                                                                                                                                                                                                                                                                                                                                          |                                            |                       |     |          |          |   |            |                 |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-----------------------|-----|----------|----------|---|------------|-----------------|
| 外观检测<br>Appearance                                                                                        | 针尖检验<br>Needle Tip Inspection                     | No burr, tip, tip (barb), white spot (bald tip), rust, oil and other defects, after screwing the cap, there is no obvious sticky coating material and serious burr etc<br>针尖不得有毛刺,翘尖,碰尖(倒钩),白点(秃尖),锈迹,油污等缺陷,拧帽后无明显粘包料和严重毛刺                                                                                                                               | 目测/显微镜<br>Visual Inspection/<br>Microscope | HJD003                | S-3 | 0.4      | 32       | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 清洁度<br>Cleanliness                                | Clean and free of dust, grease and dirt<br>清洁、无灰尘、油污、脏污                                                                                                                                                                                                                                                                                                  | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125      | 3 | 4          | 合格<br>Qualified |
| 性能检测<br>Performance                                                                                       | 针体与针柄牢固度<br>Firmness of needle and plastic handle | 11: 16G-38G≥5N<br>其余型号: 16G-30G≥22N, 31-38G≥5N                                                                                                                                                                                                                                                                                                           | 牢固度测试仪<br>Strength Tester                  | HJE065                | S-2 | 1.0      | 13       | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 穿刺力<br>Puncture Force                             | 26G-38G≤1N; 20G-25G≤1.5N; 18G-19G≤2N;<br>16G<4N                                                                                                                                                                                                                                                                                                          | 穿刺力测试仪<br>Puncture Force Teter             | HJE017                | S-2 | 1.0      | 13       | 0 | 1          | 合格<br>Qualified |
| 耐腐蚀性<br>Corrosion Resistance                                                                              |                                                   | The corrosion resistance of the needle tip should reach grade b or above<br>针尖的耐腐蚀性能不低于b级要求                                                                                                                                                                                                                                                              | 目测<br>Visual Inspection                    | NA                    | S-4 | 0.65     | 125      | 2 | 3          | 合格<br>Qualified |
| 包装<br>Package                                                                                             | 产品信息<br>Product Info                              | Correct shipping mark, accessories, packing method, inkjet, labeling position and product<br>唛头,附件,包装方式,喷码,贴标位置,产品正确                                                                                                                                                                                                                                     | 目测<br>Visual Inspection                    | NA                    | S-2 | Ac0, Rel | 13盒      | 0 | 1          | 合格<br>Qualified |
|                                                                                                           | 数量<br>Quantity                                    | Correct quantity<br>包装数量准确,无偏差                                                                                                                                                                                                                                                                                                                           | 数数/电子秤<br>Count/Electronic Balance         | HJF101                | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           | 封口/外观<br>Seal/Appearance                          | Clean and free of dust, grease and dirt<br>外观保持清洁等: 无灰尘,油污,脏污                                                                                                                                                                                                                                                                                            | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           |                                                   | No open paste, missing paste, dirty paste, no obvious cutting skew, color difference, forming defects, linear defects, spot defects, printing or coding defects, folds, damage, residual material, residual glue, overflow glue, burst edge, burst line, pressed products, etc<br>无开贴,漏贴,脏贴,无明显的裁切歪斜,色差,成型缺陷,线状缺陷,点状缺陷,印刷或喷码缺陷,褶皱,破损,残料,残胶,溢胶,爆边,爆线,压产品等 | 目测<br>Visual Inspection                    | NA                    | S-4 | 1.0      | 125盒     | 3 | 4          | 合格<br>Qualified |
|                                                                                                           |                                                   | No blood, hair, insect<br>无血渍,毛发,昆虫                                                                                                                                                                                                                                                                                                                      | 目测<br>Visual Inspection                    | NA                    | S-4 | Ac0, Rel | 125盒     | 0 | 1          | 合格<br>Qualified |
| 灭菌/Sterilization                                                                                          |                                                   | Check the certificate, and meet requirements, and the survival probability of microorganism is ≤1*10 <sup>-6</sup><br>核对辐照证明书满足要求,微生物存活概率≤1*10 <sup>-6</sup>                                                                                                                                                                                             | 目测<br>Visual Inspection                    | 核对结果/Check the result |     |          |          |   |            | 合格<br>Qualified |
| 原始数据见附表《常规针最终检测数据记录》/Detailed raw data refer to attached Inspection Result for Disposable Sterile Lancets |                                                   |                                                                                                                                                                                                                                                                                                                                                          |                                            |                       |     |          |          |   |            |                 |
| 检验结论/Inspection Conclusion:                                                                               |                                                   | 合格/Qualified                                                                                                                                                                                                                                                                                                                                             |                                            |                       |     |          |          |   |            |                 |
| 判定结果/Result                                                                                               |                                                   | 合格/Qualified                                                                                                                                                                                                                                                                                                                                             |                                            |                       |     |          |          |   |            |                 |
| 检验人员/Inspector:                                                                                           |                                                   | 杨明                                                                                                                                                                                                                                                                                                                                                       |                                            |                       |     |          | 日期/Date: |   | 2024-12-25 |                 |
| QC主管/QC Manager:                                                                                          |                                                   | 张                                                                                                                                                                                                                                                                                                                                                        |                                            |                       |     |          | 日期/Date: |   | 2024-12-25 |                 |

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# 辐照证明书

CERTIFICATE OF IRRADIATION

证书编号：202412010  
Certificate No.:

加工编号：2024121001  
Process Code No.:

天津爱邦辐射技术有限公司

TIANJIN ELPONT RADIATION TECHNOLOGY CO., LTD.

地址(Add): 天津市武清区泗村镇功能开发区

Si Cun Dian function development zone, Wuqing, Tianjin, China

电话(TEL): +86(0)22 29429066

传真(FAX): +86(0)22 29429066

邮政编码: 301709

公司网址: <http://www.tjelpont.com>

顾客名称：天津华鸿科技股份有限公司  
Customer:

| 产品名称<br>Article description | 包装规格(厘米)<br>Carton Size(cm) | 产品批号<br>Article Lot No. | 数量(箱)<br>Carton Qty(cs) | 毛重(公斤)<br>G. W(kgs) |
|-----------------------------|-----------------------------|-------------------------|-------------------------|---------------------|
| 一次性使用末梢采血针                  | 25.5*21.4*14.2              | 2410123                 | 11520                   | 18432               |

这批产品已经过电子射线辐射。

THE PRODUCTS HAVE BEEN IRRADIATED BY ELECTRON BEAM.

加工编号：2024121001  
Process Code No.:

辐照结束的日期：2024-12-10  
Irradiation lot finish date

顾客要求最低平均吸收剂量：25 kGy  
Minimum specified dose:

最低有效吸收剂量：26.32 kGy  
Minimum inspection area

顾客要求最高平均吸收剂量：50 kGy  
Maximum specified dose:

最高耐受吸收剂量：42.85 kGy  
Maximum inspection area

检验员：王丽娜  
Inspector:

审核：朱玉辉  
Approved:

日期：2024.12.10  
Date:

天津爱邦辐射技术有限公司  
TIANJIN ELPONT RADIATION TECHNOLOGY CO., LTD.

检验专用章

(本证明书的影印件与原件一致。The copy of this certificate is consistent with the original.)



## Sterility Test Report

## 无菌试验报告

Test Date 实验日期: 2024.12.11

Report Date 报告日期: 2024.12.25

|                                                                                          |                                                                                                                                                                                                                        |                                                                   |                                                                                                                          |
|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Product Name<br>样品名称                                                                     | 一次性使用末梢采血针                                                                                                                                                                                                             | PO No.<br>订单号                                                     | HHT24101815                                                                                                              |
| Certificate of<br>Irradiation No<br>辐照证明书<br>编号                                          | 202412010                                                                                                                                                                                                              | Inspection<br>Criteria<br>检验依据                                    | Pharmacopoeia of the<br>People's Republic of<br>China (2020) 中华人民共和国药典 (2020 版)<br>GB/T 19973-2:2018<br>GB/T14233.2-2005 |
| Product Code<br>产品编码                                                                     | C.P. 01K. 28. NX2-50H01                                                                                                                                                                                                | Lot No.<br>批号                                                     | 2410123                                                                                                                  |
| Cultivation time<br>of test product<br>供试品培养时间                                           | 14 天                                                                                                                                                                                                                   | Temperature<br>温 度                                                | Bacteria 细菌: 32℃<br>Fungus 真菌: 23℃                                                                                       |
| Culture time of<br>positive control<br>and sedimentation<br>bacteria<br>阳性对照及沉降菌<br>培养时间 | 3 天                                                                                                                                                                                                                    | Temperature<br>温 度                                                | 32℃                                                                                                                      |
| Incubator number<br>培养箱编号                                                                | HJE011                                                                                                                                                                                                                 | Incubator number<br>培养箱编号                                         | HJE048                                                                                                                   |
| Pipette number<br>移液枪编号                                                                  | HJE416                                                                                                                                                                                                                 | Number of<br>high-pressure<br>steam<br>sterilization<br>高压蒸汽灭菌锅编号 | HJE047                                                                                                                   |
| Name, batch number<br>and purpose of<br>medium 培养基名称<br>批号、用途                            | 1. Thioglycollate Medium (for bacteria testing) 硫乙醇酸盐培养基 (用于细菌检测): 230717<br>2. TSB (for fungus testing) 胰酪大豆胨液体培养基 (用于真菌检测): 230529<br>3. TSA medium (Used for environmental monitoring) 胰酪大豆胨琼脂培养基 (用于环境监测): 2308192 |                                                                   |                                                                                                                          |
| Inoculation mode<br>接种方式                                                                 | Direct inoculation 直接接种法                                                                                                                                                                                               |                                                                   |                                                                                                                          |

版本: E, 修改次数: 1



|                                                                                                                                                                                                                |                                                                                                      |                            |                            |                          |                        |                        |                               |                |          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|----------------------------|----------------------------|--------------------------|------------------------|------------------------|-------------------------------|----------------|----------|
| Sample size<br>抽样量                                                                                                                                                                                             | 60 件                                                                                                 |                            |                            |                          |                        |                        |                               |                |          |
| Test Result<br>检 验 结 果                                                                                                                                                                                         |                                                                                                      |                            |                            |                          |                        |                        |                               |                |          |
| Identification of<br>bacteria 鉴别菌                                                                                                                                                                              | aerobe, anaerobe 需氧菌、厌氧菌<br>30℃-35℃                                                                  |                            |                            |                          |                        |                        | fungus, aerobe 真菌、需氧菌 20℃-25℃ |                |          |
| Group 组别                                                                                                                                                                                                       | sa<br>mp<br>le<br>样<br>品                                                                             | neg<br>ati<br>ve<br>阴<br>性 | pos<br>iti<br>ve<br>阳<br>性 | settling micro<br>be 沉降菌 |                        |                        | sample<br>样品                  | negative<br>阴性 | 备 注 note |
|                                                                                                                                                                                                                |                                                                                                      |                            |                            | ves<br>sel<br>1 皿<br>1   | ves<br>sel<br>2 皿<br>2 | ves<br>sel<br>3 皿<br>3 |                               |                |          |
| Cultivate Period<br>培养时间                                                                                                                                                                                       | 3<br>d                                                                                               | -                          | -                          | +                        | 0                      | 0                      | 0                             | -              | -        |
|                                                                                                                                                                                                                | 5<br>d                                                                                               | -                          | -                          |                          |                        |                        |                               | -              | -        |
|                                                                                                                                                                                                                | 7<br>d                                                                                               | -                          | -                          |                          |                        |                        |                               | -              | -        |
|                                                                                                                                                                                                                | 1<br>4<br>d                                                                                          | -                          | -                          |                          |                        |                        |                               | -              | -        |
| Conclusion<br>检测结论                                                                                                                                                                                             | After testing, the sterility test results of this batch of products are qualified<br>经检测本批产品无菌测试结果合格 |                            |                            |                          |                        |                        |                               |                |          |
| 注 Note: “-”: negative 阴性 “+”: positive 阳性<br>negative pair care for “-”, Positive pair care for “+”, Sample set for “-”<br>settling microbe/vessel ≤ 1 qualified 阴性对照管为“-”、阳性对照管为“+”、样品组为“-”<br>沉降菌/皿 ≤ 1 即为合格 |                                                                                                      |                            |                            |                          |                        |                        |                               |                |          |

Inspected by 检验人: 李斯睿

Verified by 复核人: 付永

Approved by 批准人: 李锐

Date 日期: 2024-12-25

Date 日期: 2024-12-25

Date 日期: 2024-12-25

版本: E, 修改次数: 1

