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| --- | --- | --- | --- | --- | --- | --- | --- |
| **规范** | | | 文件编号 | |  | | |
| **\*\*物料检验标准** | | | 版 本 | | A0 | | |
| 页 数 | | 第 1 页 共X页 | | |
| 编制部门 | | 质量部 | | |
| 生效日期 | |  | | |
| 编 制 |  | 审核 | |  | | 批准 |  |

1. **物料描述**

|  |  |  |  |
| --- | --- | --- | --- |
| 物料名称 |  | 规格型号 |  |
| 物料编号 |  | 物料类别 |  |

1. **检验内容**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求 | 抽样计划 | 接收标准 | 检测工具 | 检测方法 |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 来料检验报告 | | | | | | | | | | | | | | | | | | | | | |  | |
| 文件编号：　　　　　　版本：　　　　ＮＯ. | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |  |  |
| 物料编号 | |  | | | | 物料名称 | | |  | | | | | 规格型号 | | | |  | | | | | |
| 送检日期 | |  | | | | 采购订单编号 | | |  | | | | | 物料批号 | | | |  | | | | | |
| 送检数量 | |  | | | | 检验数量 | | |  | | | | | 检验日期 | | | |  | | | | | |
| 抽样计划 | |  | | | | □ 正常 □放宽 □加严 □全检 | | | | | | | | | | | | | | | | | |
| 检验依据 | |  | | | | | | | | | | | | | | | | | | | | | |
| 检验设备 | |  | | | | | | | | | | | | | | | | | | | | | |
| 序号 | 检验项目 | | | 接收标准 | | | 检验结果 | | | | | | | | | | | | | | | | |
| 1 | 2 | | 3 | | 4 | 5 | | | 6 | 7 | 8 | | 9 | 10 | | 11 | |
| 1 |  | | |  | | |  |  | |  | |  |  | | |  |  |  | |  |  | |  | |
| 2 |  | | |  | | |  |  | |  | |  |  | | |  |  |  | |  |  | |  | |
| 3 |  | | |  | | |  |  | |  | |  |  | | |  |  |  | |  |  | |  | |
| 检验结果说明： | | | | | | | | | | | | | | | | | | | | | | | |
| 抽检统计 | | | 合格品数量 pcs  不合格品数量 pcs | | | | | | | | 审核： | | | | | | | | | | | | |
| 最终结果 | | | （ ）批合格 （ ）批拒收 | | | | | | | |
| 检验员： | | | | | | | | | | |
| （如需要特采则需填写下）处理意见及部门会签 | | | | | | | | | | | | | | | | | | | | | | | |
| 拣货（ ）加工（ ） | | | | | 部门 | 质量部 | | | 生产部 | | | | | | 研发部 | | | | 采购部 | | | | |
| 接受（ ）特采（ ） | | | | | 意见 |  | | |  | | | | | |  | | | |  | | | | |
| 退货（ ）作废（ ） | | | | | 签名 |  | | |  | | | | | |  | | | |  | | | | |

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| **规范** | | | 文件编号 | |  | | |
| 成品检验标准 | | | 版 本 | | A0 | | |
| 页 数 | | 第 1 页 共X页 | | |
| 编制部门 | | 质量部 | | |
| 生效日期 | |  | | |
| 编 制 |  | 审核 | |  | | 批准 |  |

1. **产品描述**

|  |  |  |  |
| --- | --- | --- | --- |
| 产品名称 |  | | |
| 产品编号 |  | 规格型号 |  |

1. **抽样标准**

规定的全部检验项目按照交检批次逐批全数检验。

1. **检验内容**
   1. 安全性检查

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求 | 接收标准 | 检测工具 | 检测方法 |
| 1 | 外壳漏电流 |  |  |  |  |
| 2 | 患者漏电流 |  |  |  |  |
| 3 | 电介质强度 |  |  |  |  |

* 1. 外观与结构检验【以下标准要求及接收标准仅为举例说明，请结合产品实际外观检查要求编写】

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求 | 接收标准 | 检测工具 | 检测方法 |
| 1 | 产品表面 | 外观光滑整洁、色泽均匀、无划痕、破损、变形； | 外观光滑整洁、色泽均匀、无划痕、破损、变形； | 目视 | 目视检测对象， |
| 2 | 标签及标识 | 标签及标识文字清晰、无缺划、无模糊，粘贴平整牢固 | 标签及标识文字清晰、无缺划、无模糊，粘贴平整牢固、无脱落 |  |  |
| 3 | ..... |  |  |  |  |

* 1. **性能检验【以下标准要求及接收标准仅为举例说明，请结合产品实际外观检查要求编写】**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求 | 接收标准 | 检测工具 | 检测方法 |
| 1 | 软件版本号 | V 1 | V 1 | 目视 |  |
| 2 | 心率测量范围 | 40bpm～120bpm | 40bpm～120bpm |  |  |
| 3 | 心率测量误差 | ≤±5bpm. | ≤±5bpm |  |  |
| 4 | 呼吸值测量范围 | 10bpm～35bpm | 10bpm～35bpm |  |  |
| 5 | 呼吸值测量误差 | ±5bpm | ±5bpm |  |  |
| 6 | 电池续航时间 | 续航时间超过24h | 续航时间超过24h |  |  |
|  | ..... |  |  |  |  |

* 1. **功能检验【以下检验项目及检测方法仅为举例说明，请结合产品实际外观检查要求编写】**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求 | 接收标准 | 检测工具 | 检测方法 |
| 1 | 报警功能 | 对心跳数和呼吸数异常状态进行报警 | 超出心率及呼吸值范围时，自动报警 |  | 分别输入心率30bpm及130bpm，呼吸值5bpm及40bpm，检查是否响起警报声 |
| 2 | 供电功能 |  |  |  |  |
| 3 | 呼叫功能 |  |  |  |  |
| 4 | 数据通信功能 |  |  |  |  |
| 5 | 实时监测功能 |  |  |  |  |
|  | ...... |  |  |  |  |

成品检验报告

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| 文件编号：　　　　　　版本：　　　　ＮＯ. | | | | | | | | | | | | | | | | | | | | | |
| 产品名称 | |  | | | 产品编号 | | |  | | | | | 规格型号 | | |  | | | |
| 送检日期 | |  | | | 生产订单编号 | | |  | | | | | 生产批次 | | |  | | | |
| 送检数量 | |  | | | 检验数量 | | |  | | | | | 检验日期 | | |  | | | |
| 检验依据 | |  | | | | | | | | | | | | | | | | | |
| 检验设备 | |  | | | | | | | | | | | | | | | | | |
| 序号 | 检验项目 | | | 接收标准 | | 检验结果 | | | | | | | | | | | | | |
| 1 | 2 | | 3 | | 4 | 5 | | 6 | 7 | 8 | 9 | 10 | 11 | |
| 1 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 2 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 3 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 4 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 5 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 6 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 检验结果说明： | | | | | | | | | | | | | | | | | | | |
| 检验结果 | | | 合格品数量 pcs  不合格品数量 pcs | | | | | | | 审核： | | | | | | | | | |
| 检验员： | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **规范** | | | 文件编号 | |  | | |
| 包装检验标准 | | | 版 本 | | A0 | | |
| 页 数 | | 第 1 页 共X页 | | |
| 编制部门 | | 质量部 | | |
| 生效日期 | |  | | |
| 编 制 |  | 审核 | |  | | 批准 |  |

1. **产品描述**

|  |  |  |  |
| --- | --- | --- | --- |
| 产品名称 |  | | |
| 产品编号 |  | 规格型号 |  |

1. **抽样标准**
2. **检验内容**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 序号 | 检验项目 | 标准要求  【以下为举例说明，请结合产品实际外观检查要求编写】 | 接收标准 | 检测工具 | 检测方法 |
| 1 | 附件 | 合格证1份、说明书1份、...... |  |  |  |
| 2 | 外观 | 包装完整，无污渍、划痕...... |  |  |  |
| 3 | ...... |  |  |  |  |

包装检验报告

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| 文件编号：　　　　　　版本：　　　　ＮＯ. | | | | | | | | | | | | | | | | | | | | | |
| 产品名称 | |  | | | 产品编号 | | |  | | | | | 规格型号 | | |  | | | |
| 送检日期 | |  | | | 生产订单编号 | | |  | | | | | 生产批次 | | |  | | | |
| 送检数量 | |  | | | 检验数量 | | |  | | | | | 检验日期 | | |  | | | |
| 抽样计划 | |  | | | | | | | | | | | | | | | | | |
| 检验依据 | |  | | | | | | | | | | | | | | | | | |
| 检验设备 | |  | | | | | | | | | | | | | | | | | |
| 序号 | 检验项目 | | | 接收标准 | | 检验结果 | | | | | | | | | | | | | |
| 1 | 2 | | 3 | | 4 | 5 | | 6 | 7 | 8 | 9 | 10 | 11 | |
| 1 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 2 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 3 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 4 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 5 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 6 |  | | |  | |  |  | |  | |  |  | |  |  |  |  |  |  | |
| 检验结果说明： | | | | | | | | | | | | | | | | | | | |
| 抽样统计 | | | 合格品数量 pcs  不合格品数量 pcs | | | | | | | 审核： | | | | | | | | | |
| 检验结果 | | | （ ）批合格 （ ）批拒收 | | | | | | |
| 检验员： | | | | | | | | | |

免责声明：

模板内容仅根据当前法规及行业常规实践经验进行编写，仅供参考使用。

质量管理体系的合规需要结合公司实际情况、体系文件、体系运行记录/文档等综合考虑，企业直接采用不代表合规，请根据最新法规及公司实际工作流程等进行补充、细化和调整，并有效运行质量管理体系。