

# Computer software confirms the control Procedure

## 计算机软件确认控制程序

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### History/修改履历

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## 1. Purpose and scope/目的和适用范围

Confirm the computer software to verify the ability of the process to achieve the planned results.

通过对计算机软件进行确认，以证实该过程实现所策划结果的能力。

Applicable to the software used in the company's production and service processes, monitoring and measurement processes, and software tools needed in the software development process; Such as production ERP software and inspection software.

适用于本公司生产和服务过程、监视测量过程所用的软件、研发过程中所需要使用到的软件工具；如生产用 ERP 软件及检验软件等。

## 2. Reference document/参考文件

ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

医疗器械 质量管理体系 用于法规的要求

## 3. Abbreviations and Definitions/缩略语与定义

### 3.1. Abbreviations/缩略语

N.a

### 3.2. Definitions/定义

#### 3.2.1. Black box testing/黑盒测试

The system (software and hardware) is regarded as a black box that cannot be opened. Without considering the internal structure and characteristics of the system, the tester only relies on the software tool requirement specification to determine the test data from possible input conditions and output conditions, that is, according to the function or external characteristics of the system. Design test cases (e.g. functional tests).

将系统(软件和硬件)看作不能打开的黑盒,在不考虑系统内部结构和特性的情况下,测试者只依靠该软件工具需求说明书,从可能的输入条件和输出条件中确定测试数据,也就是根据系统的功能或外部特性,设计测试用例(例如功能测试)。

#### 3.2.2. Installation confirmation/安装确认

Verify that the system is installed in accordance with design standards, and confirm the required installation environment, software and hardware technical documents, drawings, and operation manuals.

确认系统的安装符合设计标准,并对所需要的安装环境、软件及硬件的技术资料、图纸、操作手册等文件进行确认。

#### 3.2.3. Run (operation) confirmation/运行(操作)确认

Verify that the system functions meet user requirements. System operation verification shall be performed in a test environment isolated from the normal working environment, but shall simulate the normal working environment.

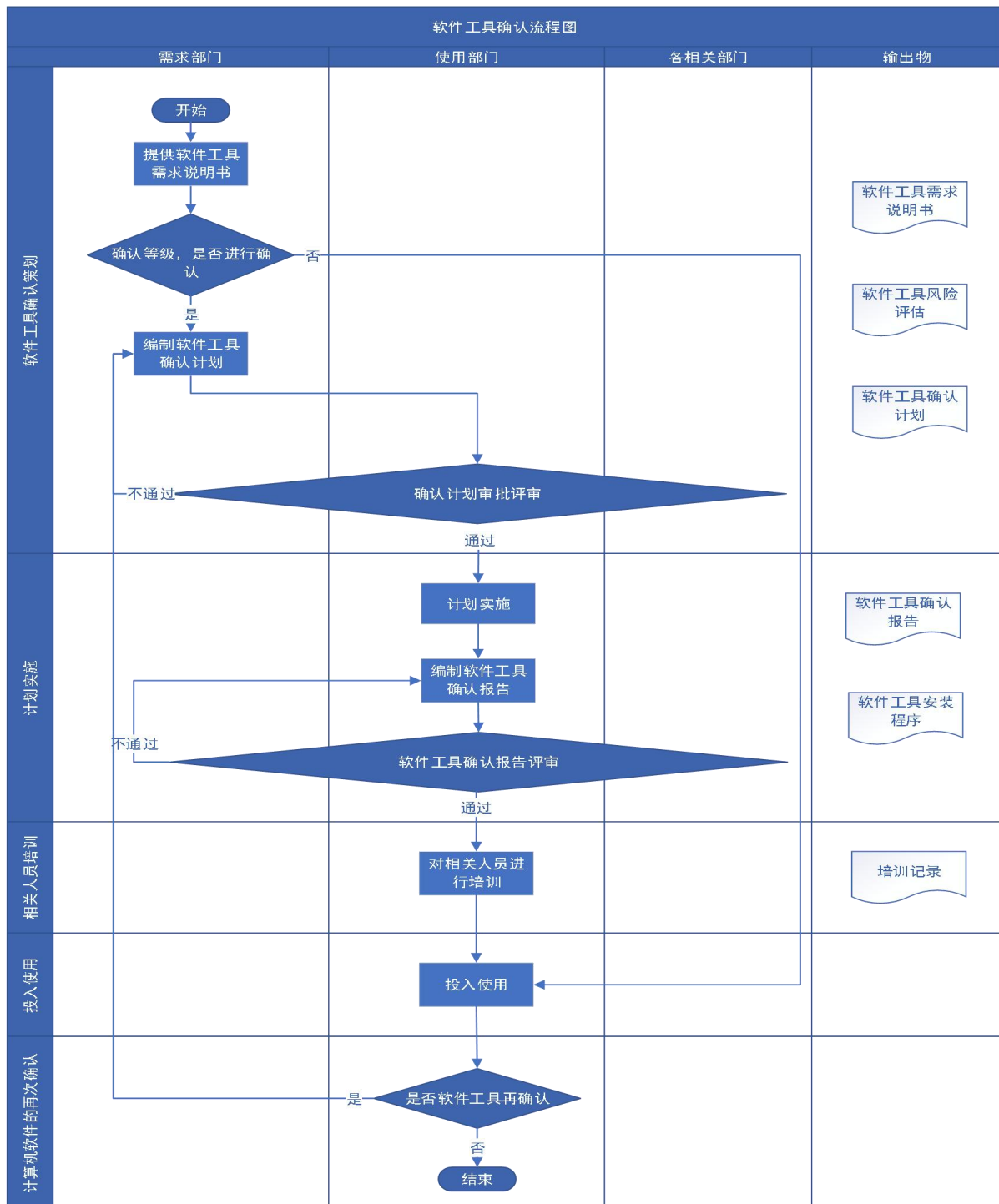
确认系统的各项运作功能符合用户需求标准。系统运行确认应在一个与正常工作环境隔离的测试环境下实施,但应模拟正常工作环境。

#### **3.2.4. Performance (process) confirmation/性能(工艺)确认**

To confirm the effectiveness and stability of the system operation process, it should be tested under normal working environment. The test project is based on the overall effect of the system operation (such as testing the quality characteristics of the product produced), and the test should be repeated no less than three times under normal working environment (under the same conditions).

确认系统运行过程的有效性和稳定性，应在正常工作环境下进行测试。测试项目依据对系统运行希望达到的整体效果而定(如对生产出的产品质量各项特性进行测试)，测试应在正常工作环境下(相同条件下)重复不低于三次。

## 4. Flow chart/流程图



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