



## Manufacturing Equipment

A medical device manufacturer has decided to automate the printing and inspecting of a label prior to it being applied to the carton of a device.

### Software Intended Use

The label verification (LV) system is used to print and inspect labels and only allows labels that have passed inspection to be applied to the carton. The results of the inspection are displayed on screen and written to a database. The system interacts with a label application system and needs to be 21 CFR Part 11 compliant as it creates and maintains quality records. The process steps for using the LV system station are as follows:

- Product information is scanned from the shop floor paperwork, so the system knows how many labels to print.
- Upon operator command, the LV system starts to print and inspect labels.
- Labels which are accepted are sent to the label application system where they will be applied to cartons.
- Labels which fail inspection are sent to a reject bin.
- The first and last inspection images from each batch are saved to a secure location.

The LV system has the following controls:

- Alarm when a label fails inspection.
- Alarm when no labels are printed.



### Risk Based Assurance Approach

The manufacturer determines that the output from the LV system has a direct impact on device quality and safety. To assess the level of validation required, the manufacturer must understand the patient safety risk posed by the labelling process. This is understood by reviewing the appropriate process risk management document (e.g. PFMEA). In this instance, the labelling process risk level was assigned a high risk as if the incorrect label was applied then irreversible damage could be caused to a patient.

With this understanding of the system, the manufacturer is now in a position to look at each software feature/function and complete the software risk assessment called for by this guidance.

The features associated with this system are: Barcode Scanning, Label Printing, Label Inspection, Label Application and Saving of Images.

Applying risk assessment on each of these features, the manufacturer classified Label Inspection and Label Application to be high risk features. The remaining features were classified as medium risk.

The manufacturer conducts the following activities to demonstrate the LV print and inspection feature performs as intended:

- Details the intended use of the LV system and its associated risk.
- Develops a test plan describing the approach that will be taken for both high and medium features.
  - For high risk features:
    - Use formal scripted testing with test objectives, test cases (step-by-step procedures), and expected results.
    - Documents a test result for each test case, indicating which tests pass/fail.
    - Supplements the formal scripted testing with ad-hoc testing.
    - Details and dispositions any issues found during testing.
    - Records who performed testing and when the date(s) when it occurred.
  - For medium risk features:
    - Use Exploratory Testing by establishing high level test plan objectives for each feature (no step-by-step procedure is necessary).
    - Documents a result for each test plan objective, indicating which tests pass/fail.
    - Supplements the Exploratory Testing with ad-hoc testing.
    - Details and dispositions any issues found during testing.
    - Records who performed testing and when the date(s) when it occurred.
- Creates a conclusion statement summarizing the validated state of the LV system.