Revision History for PRC097510 Rev A

|  |  |
| --- | --- |
| **SUMMARY OF CHANGES** | |
| Revision No. | Description of Change |
| A | Original Document |

|  |  |
| --- | --- |
| **INSTALLATION QUALIFICATION PROTOCOL** | |
| Document Title: | Automated Label Applier E20172 |
| Document Number / Revision: | PRC0097510Rev A |
| Site / Location: | Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juárez, Chihuahua, 32575, México. |
| Project / Area: | Megadyne Packaging Line 174 |
| Equipment: | Automated Label Applier |
| Equipment Supplier: | PROD Design |
| Validation Assessment Reference: | DC003495 |

# 

# Document Approvals

Document Type as per Approval Matrix CP0160: Protocol – Installation Qualification.

Governance: Lifecycle Engineering - Post- Stabilization

| Function | Name | Signature | Date |
| --- | --- | --- | --- |
| **Originator** | Ricardo Miranda | eSig in Epicenter System | Electronic Date in Epicenter System |
| MEST Equipment Engineer | Javier Diaz | eSig in Epicenter System | Electronic Date in Epicenter System |
| Plant Quality Engineer | Victor Cantu | eSig in Epicenter System | Electronic Date in Epicenter System |
| Business Unit Manufacturing Engineer | Alan Arrieta | eSig in Epicenter System | Electronic Date in Epicenter System |
| Preventative Maintenance Engineer | Cesar Montoya | eSig in Epicenter System | Electronic Date in Epicenter System |
| Lifecycle Quality Engineer | Ihsan Samara | Electronic Signature in Epicenter | Electronic Signature in Epicenter |

# Purpose

The purpose of this installation qualification is to establish by objective evidence that E20172 Automated Label Applier (Maximo ID: ES4457) have been correctly installed and will perform as intended.

This is an initial and full validation for a new equipment used in the packaging station located at Megadyne line 174 in Independencia’s newly constructed Controlled Manufacturing Environment.

# Scope & Background

The scope of this installation qualification is limited to E20172 Automated Label Applier (Maximo ID: ES4457) Installed in production packaging line 174.

The following Table lists the product codes to be processed in this equipment.

|  |  |
| --- | --- |
| **Code** | **Description** |
| 0012 | EZ Clean 2.5" Blade |
| 0012A | EZ Clean 2.75" Blade |
| 0012AM | EZ Clean 2.75" Modified Blade |
| 0014 | EZ Clean 6.5" Blade |
| 0014A | EZ Clean Blade, 4.0" |
| 0014AM | EZ Clean Modified Blade, 4.0" |
| 0014M | EZ Clean Modified Flat Blade, 6.5" |
| 0012M | EZ Clean 2.5" Modified Blade |
| 0013 | EZ Clean 2.75" Needle |
| 0013M | EZ Clean Modified Needle, 2.75" |
| 0118 | EZ Clean Sharp Needle, 2.0" |
| 0118A | EZ Clean Sharp Needle, 2.5" |

Table 1: Product codes for Packaging

## Equipment information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment Name** | **Equipment Number** | **Maximo ID Number** | **Supplier** | **Serial #** |
| Automated Label Applier | E20172 | ES4457 | PROD Design | PROD-20145A |

Table 2: Equipment information

## Process information

The Automated Label Applier is part of the Megadyne packaging Line 174 and intended for printing and applying printed labels on the unit box.

## Product information

Product applicable for this Installation Qualification protocol listed in Table 1.

## Out of Scope

All equipment that is not listed in Table 2 is out of the scope of this installation qualification.

# Definitions, Terms and Abbreviations

Refer to 100632965 Franchise Glossary for Validation (Shared) for terminology and abbreviations used in the Ethicon, Ethicon Endo Surgery, and Cardiovascular and Specialty Solutions (CSS) validation program.

# Roles & Responsibilities

Equipment Set Up Originator or Equipment Engineer

Training Originator or Designee

Perform machine operation Originator or Designee

Documentation of Test Results Originator or Quality Engineer

Summarization of Results Originator or Quality Engineer

Overall conduct protocol Originator or Designee

Review of executed IQ Protocol Quality Engineer

Safety Requirements EES Safety Engineer

Supervise Installation activities Facilities Engineer

Energy Management System Facilities Engineer

Testing Equipment Contractor

Calibration Current Contractor

PM Current Contractor

# Acceptance Criteria

All equipment listed in Table 2 must successfully pass the requirements of sections 12 and 13 of this PRC097510 Rev A protocol.

Final approval of the IQ Report verifies the acceptance criteria have been met.

# Pre-Requisites

The purpose of this section is to ensure that the validation deliverables preceding this stage of the validation cycle have been completed approved.

* 1. Ensure that all materials required to execute the protocol are available.
  2. Ensure that the protocol has been approved.
  3. All training documents shall be attached to the completion report of this protocol.
  4. Equipment must be installed in the line and properly connected to AC, DC and / or compressed air as needed
  5. EH&S evaluation shall be completed prior the execution of this protocol, results must be included as part of the Completion Report PRC097511 Rev. A
  6. Preventive Maintenance should be completed prior the execution of this protocol.

# Deviation Handling

If deviations occur during the execution of this Installation Qualification, they will be documented per instructions in PR-0000089 Franchise Procedure for Validation (Shared). All deviations shall be documented in the Installation Qualification Report.

# Reference Documents

The following documents are used to develop and support this Installation Qualification Protocol.

| Document Number | Document Title |
| --- | --- |
| PRC094976 Rev E | Criticality Assessment. |
| DC003495 Rev A | Transfer of Megadyne Electrodes Manufacturing Process to Ethicon Independencia |
| WE0020 Rev. CH | Protocols and Engineering Studies. |
| FRM002746 Rev B | EHS Assessment Form. |
| PR-0000372 Rev 22 | Franchise Procedure for Ethicon Training Process |
| FB003341 Rev A | Validation Master Plan for MIMAS project |

# Table 3 – References

# Signature Log & protocol training Log

**Signature Log Objective**: To identify the personnel participating in the qualification activities.

Personnel involved in the execution of this protocol not familiar with the equipment, will be trained and documented on FM-0000809 which will be added in the Completion Report of this Installation Qualification Protocol.

# List of Calibrated Instruments used in the execution of the protocol

**Objective**: To summarize the calibrated instruments used in the execution of the protocol.

**Procedure**: In the table below, list all instruments used in the execution of this protocol. The calibration requirements are outlined in WE0166 Rev AX. The completed table will be attached in the Completion Report.

| Instrument / Equipment Unique Identifier | | Manufacturer / Description | | Calibration Due Date |
| --- | --- | --- | --- | --- |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
| **Comments** |  | | | |
| **Performed By:** | Signature: | | **Date:** | |
| **Reviewed by:** | Signature: | | **Date:** | |

# Installation Qualification Test Scripts

## Verification of Pre-IQ Activity Completion

**Objective**: To confirm the completion of planned pre-IQ activity.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual result must satisfy the Acceptance criteria for each test case.

**Pre-Requisites**: n/a

| Reference # | Test / Test Procedure | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- |
|  | **Test:**  IQ Protocol Approved.  PRC097510 Rev A  **Test Procedure:**  Review of status of PRC097510 Rev A in Epicenter | **Acceptance Criteria:**  IQ Protocol must be released in Epicenter prior to execution. |  |  |  |
|  | **Test:**  Criticality Approved.  PRC094976 Rev E  **Test Procedure:**  Review of status of PRC094976 Rev C in Epicenter | **Acceptance Criteria:**  Criticality must be released in Epicenter prior to execution. |  |  |  |
|  | **Test:**  Completion Report MOCCME PRC097232 Rev A  **Test Procedure:**  Review of status of PRC097232 Rev A in Epicenter | **Acceptance Criteria:**  Completion Report MOCCME must be released in Epicenter prior to execution. |  |  |  |
|  |  |  |  |  |  |
| **Comments:** | |  | | | |
| **Performed By:** | | Signature: | | Date: |  |
| Reviewed by: | | Signature: | | Date: |  |

## Verification of Engineering Documentation

**Objective**: To verify that all planned Engineering documentation with the equipment under scope has been received by the site.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: As per test scripts.

**Pre-Requisites**: N/A

| **Reference #** | **Test / Test Procedure** | **Acceptance Criteria** | **Actual Result** | **PASS / FAIL** | **Initials / Date:** |
| --- | --- | --- | --- | --- | --- |
| **12.2.1** | **Test:**  Equipment Drawing E20172  **Test Procedure:**  Review of status of Automated label Applier E20172 in Epicenter. | **Acceptance Criteria:**  Equipment drawing E20172 Rev A is in released status in Epicenter. |  |  |  |
| **Comments:** | |  | | | |
| **Performed By:** | | Signature: | | **Date:** |  |
| **Reviewed by:** | | Signature: | | **Date:** |  |

## Verification of Equipment and Ancillary System Installation

**Objective**: To verify that the Equipment has been received as expected and that installation is in accordance with expectations.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual results must satisfy the acceptance criteria for each test case.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | | PASS / FAIL | | Initials / Date: |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Test:  Verify all the safety guards are present and are in good conditions on the Automated Label Applier E20172.  Test Procedure:  Visually verify the guards are installed on the Automated Label Applier E20172. | | Safety guards are present  and are in good conditions on the Automated Label Applier E20172.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  | |  | |  |
|  | Test:  Verify all the electrical connections for equipment listed in Table 2 are in good conditions.  Test Procedure:  Visually verify the electrical connections for equipment listed in Table 2 are in good conditions. | | Electrical connections for Equipment listed in Table 2 are in good conditions.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  | |  | |  |
|  | Test:  Verify all the electrical and pneumatic drops.  Test Procedure:  Using Multimeter to verify voltage on drop, using air gauge to verify pressure in the drop gauge numbers to be recorded in actual results | | Acceptance Criteria:  Electrical drop has a voltage of 120V +/-10%.  Verify the drop air Pressure on the Automated Label Applier E20172 min 60 PSI.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. | Voltage: \_\_\_\_\_\_\_\_\_\_\_\_VAC  Pressure: \_\_\_\_\_\_\_\_\_\_\_ PSI | |  | |  |
| Comments: | |  | | | | | | |
| Performed By: | | Signature: | | | Date: | |  | |
| Reviewed by: | | Signature: | | | Date: | |  | |

## Verification of Equipment User Requirements Specifications

**Objective**: To verify the attainment of User Requirements as documented

**Procedure**: Execute as pert test script procedure. The acceptance criteria source should be agreed / approved in advance.

**Acceptance Criteria**: As per test script and acceptance criteria source.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- |
|  | **Test:** Control Cabinet integration.  **Test Procedure:**  Visual verification of the E20172 Control Cabinet presence and integrated. | **Acceptance Criteria :** Control cabinet is present and integrated on the Automated Label Applier E20172. |  |  |  |
|  |  |  |  |  |  |
|  | **Test:** Guard  **Test Procedure:**  Visual verification of Guard  Presence on the Automated Label Applier E20172. | **Acceptance Criteria :** Guards are installed correctly on the Automated Label Applier E20172.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  |  |  |
|  | **Test:** Curtain  **Test Procedure:**  Visual verification of Curtains  presence on the Automated Label Applier E20172. | **Acceptance Criteria :** Curtains are installed correctly on the Automated Label Applier E20172.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  |  |  |
|  |  |  |  |  |  |
|  | **Test:** (HMI) Panel View  **Test Procedure:**  Visual verification of the Panel View (HMI) presence on the Automated Label Applier E20172. | **Acceptance Criteria :**  Panel View (HMI) installed on the Automated Label Applier E20172. |  |  |  |
|  | **Test:** Emergency Stop button (E-Stop)  **Test Procedure:**  Visual verification of the Emergency  Stop button (E-Stop) presence, readily accessible and its correct identification. | **Acceptance Criteria :**  The Emergency Stop button (E-Stop) is properly installed, readily accessible and identified on the Automated Label Applier E20172.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  |  |  |
|  | **Test:** Machine status lights  **Test Procedure:**  Visual verification of the machine status lights presence. | **Acceptance Criteria :**  Machine status lights are properly installed on the Automated Label Applier E20172. |  |  |  |
| Comments: | |  | | | |
| Performed By: | | Signature: | | Date: |  |
| Reviewed by: | | Signature: | | Date: |  |

## Verification of Connection to Utilities and Utility Supply

**Objective**: To verify and record that the utilities and services supplied to the asset are suitable.

**Procedure**: Using calibrated instruments and equipment have qualified personnel verify and record that the utilities and services supplied to the asset are suitable. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: As per test script and acceptance criteria source.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | PASS / FAIL | Reference # |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Test:**  Connect E20172 Automated Label Applier, Maximo ID ES4457 to a 120VAC power connection.  **Test Procedure:**  Connect the machine’s main power cable to an 120VAC outlet and turn it on. | | **Acceptance Criteria:**  E20172 Automated Label Applier, Maximo ID ES4457. must be connected to an electrical drop has a voltage of 120V +/-10%.  Equipment must turn on. |  |  |  |
|  | **Test:**  Connect E20172 Automated Label Applier, Maximo ID ES4457 to Air Supply connection.  **Test Procedure:**  Connect the machine to the air supply connection. | | **Acceptance Criteria:**  E20172 Automated Label Applier, Maximo ID ES4457. must be connected to a pneumatic drop  . |  |  |  |
|  |  | |  |  |  |  |
| Comments: | |  | | | | |
| Performed By: | | Signature: | | | Date: |  |
| Reviewed by: | | Signature: | | | Date: |  |

## Verification of Equipment Procedures / Work Instructions

N/A since this equipment procedures will be documented in a PQ protocol.

## Verification of Equipment Maintenance and Spare Parts

**Objective**: To verify that Equipment complies with the local maintenance procedure.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: As per test scripts.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- |
|  | **Test:**  Equipment Registry is completed.  **Test Procedure:**  Equipment Registry in Maximo using form FMWE0366.3 | **Acceptance Criteria:**  Equipment is registered as  an asset in Maximo. Form FMWE0366.3 is filled. (For evidence a Screen Shot must be show in operating status in Maximo System) Automated Label Applier E20172 (ID: ES4457).  Note: Spare part list will be attached on the completion report. |  |  |  |
| Comments: | |  | | | |
| Performed By: | | Signature: | | Date: |  |
| Reviewed by: | | Signature: | | Date: |  |

## Verification of Equipment Instrument Calibration

**Objective**: To verify that all equipment instrumentation is suitable for its intended used and calibrated, as appropriate, in accordance with calibration procedure.

**Procedure**: For each instrument embedded in the equipment verify that it is suitable for its intended use and calibrated, as appropriate, in accordance with local site calibration procedure CP0190 Calibration records shall be available as part of review and approval of the executed protocol.

**Acceptance Criteria**: Instruments shall be suitable for their intended used and calibrated to meet requirements as outlined in CP0190.

**Pre-Requisites**: N/A

| Instrument / Equipment Unique Identifier | | Manufacturer / Description | | Calibration Date | |
| --- | --- | --- | --- | --- | --- |
|  | |  | |  | |
|  | |  | |  | |
| Comments: |  | | | | |
| **Performed By:** | Signature: | | **Date:** | |  |
| **Reviewed by:** | Signature: | | **Date:** | |  |

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## Verification of Equipment Environmental Requirements

N/A. No environmental requirements are needed for this equipment.

## Verification of Environment, Health and Safety & Sustainability Requirements

**Objective**: To verify Environment, Health and Safety & Sustainability Requirements have been achieved for the equipment under scope.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual result must satisfy the Acceptance criteria for each test case.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Test:**  EHS Assessment Form FRM002746 Rev. B  **Test Procedure:**  EHS engineer must audit the safety and ergonomic conditions of this equipment using the form FRM002746 Rev B. | | **Acceptance Criteria:**  EHS Assessment Form FRM002746 Rev. B is filled and approved by an EHS engineer. |  |  |  |
| Comments: | |  | | | | |
| Performed By: | | Signature: | | | Date: |  |
| Reviewed by: | | Signature: | | | Date: |  |

## Verification of Materials of Construction / Product Contacting Materials

**Objective**: To verify that the Materials of Construction / Product Contacting Materials are as specified and that there are no detrimental effects on the process / product.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual result must satisfy the Acceptance criteria for each test case.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Test:** Verification of materials of construction according to WE0725 requirements. | | **Acceptance Criteria:**  All materials that are in contact with the product must meet the WE0725 requirements. |  |  |  |
|  | **Test Procedure:**  Review all materials that is in contact with the product must meet the WE0725 requirements. | | **Acceptance Criteria Source:**  WE0725 rev L |  |  |  |
| Comments: | |  | | | | |
| Performed By: | | Signature: | | | Date: |  |
| Reviewed by: | | Signature: | | | Date: |  |

## Verification of Computer Hardware Installation

**Objective**: To verify that Computer Hardware [Control System Software, Peripherals, Network connection etc.] has been properly supplied and installed as specified in Automated Label Applier E20172

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria** : Actual result must satisfy the acceptance criteria

**Pre-Requisites** : N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- | --- |
|  | Test:  Verification of HMI (Panel View) installation. | | Acceptance Criteria:  HMI (Panel View) of Automated Label Applier E20172 must turn on. |  |  |  |
|  | Test Procedure:  Review of HMI (Panel View) turn on | |  |  |  |  |
| Comments: | |  | | | | |
| Performed By: | | Signature: | | | Date: |  |
| Reviewed by: | | Signature: | | | Date: |  |

## Verification of Computer Software Installation

**Objective**: To verify that Computer Software [Control System Software, Peripherals, Network connection etc.] has been properly supplied and installed as specified in Automated Label Applier E20172.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria** : Actual result must satisfy the acceptance criteria

**Pre-Requisites** : N/A

| Reference # | Test / Test Procedure | | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- | --- |
|  | Test:  Verification of installed computer software.  Test Procedure:  Review all software installed in Automated Label Applier E20172. | | Acceptance Criteria:  All software (SRC003430) in Automated Label Applier E20172 computer is installed and ready to run |  |  |  |
| Comments: | |  | | | | |
| Performed By: | | Signature: | | | Date: |  |
| Reviewed by: | | Signature: | | | Date: |  |

# Functional / Operational Verification Test Scripts

## Functional Verification Testing

**Objective**: To verify the functionality of the supplied and installed equipment as specified.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual result must satisfy the Acceptance criteria for each test case.

**Pre-Requisites**: All the installation test scripts have been positively completed and reviewed prior to execution of functional verifications

| Reference # | Test / Test Procedure | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- |
|  | **Test:**  Emergency Stop functionality.  **Test Procedure:**  Once the machine is turned on, load a part, then cycle.  While part is being cycled press “E-Stop” button. | **Acceptance Criteria:**  Machine stops.  HMI shows screen of Part “Emergency Stop Pressed” message.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  |  |  |
|  | **Test:**  Interlock Curtain functionality.  **Test Procedure:**  The process must stop when a interlock curtain is interrupted. | **Acceptance Criteria:**  The process is stopped when a interlock curtain is interrupted.  Note: Procedure must be verified by EHS and attach FRM002746 in Completion Report PRC097511. |  |  |  |
|  | **Test:**  Power Outage  **Test Procedure:**  Once the machine is turned on, cut the utility supply (electrical power) and verify that equipment reacts as specified. | **Acceptance Criteria:**  When the power interruption happens, process must stop. Verify that the machine comes to a controlled stop with no risks to the operator.  Verify that the equipment can be restored to an operational state after such event. |  |  |  |
| Comments: | |  | | | |
| Performed By: | | Signature: | | Date: |  |
| Reviewed by: | | Signature: | | Date: |  |

## Operational Verification Testing

**Objective**: To verify that the equipment operates the cycle as intended.

**Procedure**: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

**Acceptance Criteria**: Actual result must satisfy the Acceptance criteria for each test case. Correct Software performance will be documented in Software Validation and will be provided in completion report.

**Pre-Requisites**: N/A

| Reference # | Test / Test Procedure | Acceptance Criteria | Actual Result | PASS / FAIL | Initials / Date: |
| --- | --- | --- | --- | --- | --- |
|  | **Test:**  Operational Testing  **Test Procedure:**  The aim of this test is to confirm that the equipment functionality operates as intended.  Run 10 samples on the Equipment. | **Acceptance Criteria:**  Equipment can successfully perform the routine. |  |  |  |
| Comments: | |  | | | |
| Performed By: | | Signature: | | Date: |  |
| Reviewed by: | | Signature: | | Date: |  |