Revision History for (PRC097511)

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

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| **INSTALLATION QUALIFICATION REPORT** | |
| **Document Title:** | Completion Report for Automated Label Applier E20172 |
| **Document Number / Revision:** | PRC097511 Rev 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 Packing Line 174 |
| **Equipment:** | Automated Label Applier |
| **Equipment Supplier:** | PROD Design |
| **Reference IQ Protocol:** | PRC097510 Rev A |

# Document Approvals

Ethicon Endo-Surgery

CP0160 Rev GY: Protocol - Installation Qualification

Governance: Lifecycle Engineering

| 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 | Irvin Rivera | 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 report is to document the objective evidence that equipment listed below for the packaging station located at Megadyne line 174 in Independencia Plant:

* E20172 Automated Label Applier (Maximo ID: ES4457).

Has been installed correctly, safely and met the installation requirements in accordance with the specifications applicable to the EES Procedures.

# Scope & Background

The scope of this installation qualification is limited to E20172 Automated Label Applier (Maximo ID: ES4457) Installed at 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 (Packaging System)

## Process information

The Automated Label Applier is part of the Packaging System located at Megadyne 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

This Completion Report covers the qualification of equipment listed in Table 2 and does not cover normal production performance which will be addressed through Operational and Performance Qualification.

# Executive Summary

Installation Qualification (IQ) has been completed for the equipment listed in Table 2, located in Independencia Plant, Ethicon Endo, following IQ Protocol PRC097510 Rev A. There were no deviations generated.

The IQ acceptance criteria defined in PRC097510 Rev A were satisfactorily met, as summarized in Attachment B. The testing conducted establishes that all key aspects of the equipment listed in Table 2 of this report are suitably considered, and the functional/operational capabilities have been verified.

# Deviations

No validation deviations were generated during the execution of the protocol. All tests met the requirements of the protocol.

# Conclusion

The Installation Qualification has established by objective evidence that all key aspects of the equipment listed in Table 2 of this installation adhere to the EES approved specification and that the recommendations of the supplier of the equipment have been suitably considered.

The Installation Qualification has met the acceptance criteria in the protocol based on the requirements outlined in PR-0000089 Rev 14Franchise Procedure for Validation (Shared).

# AttachmentS

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| Attachment No. | Title |
| Attachment A | New Equipment Sheet FMWE0366.3 |
| Attachment B | Executed Installation Qualification Protocol |
| Attachment C | Maximo Evidence |
| Attachment D | Training Record Form FM-0000809 |
| Attachment E | Calibration Records |
| Attachment F | Preventive Maintenance Records |
| Attachment G | EHS assessment |
| Attachment H | Equipment Drawing |
| Attachment I | Spare part list |
| Attachment J | WRAPS Automated Label Applier E20172 |