**Revision History for PRC097515**

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

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| **OPERATIONAL QUALIFICATION REPORT** | |
| Document Title: | Completion Report for Operational Qualification for Automated Label Applier E20172 |
| Document Number / Revision: | PRC097515 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 Packaging Line 174 |
| Product/Process: | Label Applier process for Product Codes listed in Table 2 of this Operational Qualification Report |
| Equipment: | Automated Label Applier E20172 |
| OQ Protocol Reference: | PRC097514 Rev A |
| N/A | |

# Document Approvals

The completion report will be approved per CP0160 Rev GY.

CSV-E representative to be added as required in line with Computer System Validation for Equipment Policy requirements where applicable.

| Function | Name | Signature | Date |
| --- | --- | --- | --- |
| **Originator** | Amada Cabildo | eSig in Epicenter System | Electronic Date in Epicenter System |
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| **Lifecycle Design Engineer** | Brian Walter | eSig in Epicenter System | Electronic Date in Epicenter System |
| **Approver** | Luis Gutierrez | eSig in Epicenter System | Electronic Date in Epicenter System |

# Executive Summary

Operational Qualification (OQ) PRC097514 Rev A, has been completed for the E20172 Automated Label Applier in Megadyne Packaging Line 174 at Independencia Plant, following the strategy laid out in the OQ Protocol PRC097514 Rev A. There were no Deviations.

The OQ acceptance criteria defined in PRC097514 Rev A, was satisfactorily met, as summarized in the table below. The testing establishes that the process control limits, and action levels described in the operating procedure PR001736 Rev Draft resulted in product that meets all predetermined requirements.

A sample size of 100 labelled Sales Unit Boxes for each process parameters were used for the Label Applier testing to demonstrate that the Automated Label Applier E20172 meets all predetermined specifications according to SPE004695 Rev Draft and MS00003 Rev BV.

Table 1. Summary of Testing of the label applier process using Automated Label Applier E20172.

| Parameter | Specification | Acceptance Criteria | OQ Low Parameter | OQ Nominal Parameter | OQ High Parameter | Result Pass / Fail |
| --- | --- | --- | --- | --- | --- | --- |
| Cosmetic | Unit Box Pre-Printed free of damages | No damage on the Printed box or label | **60 PSI** | **70 PSI** | **80 PSI** | **PASS** |
| Legible | Information printed legible and correct | Legible and correct information | **PASS** |
| Integrity | Label correctly attached to the Unit Box Pre-Printed | Uniform, firmly and securely attached to the Unit Box Pre-Printed | **PASS** |
| Location | Label located as per top assembly drawing | Label location matches specified location in drawing | **PASS** |

# Purpose

The report summarizes the Operational Qualification [OQ] for the Label Applier process using Automated Label Applier E20172, located in Megadyne Packaging Line 174 at Independencia Plant.

PR-0000089 Rev. 14 Franchise Procedure for Validation (Shared) defines the requirements & approach for Operational Qualification.

The purpose of this Operational Qualification Report is to document the objective evidence that the process control limits and action levels for the process using E20172 Automated Label Applier equipment results in product that meets all predetermined specification per SPE004695 Rev Draft and MS00003 Rev BV.

# Scope & background

The scope of this Operation Qualification study is for the label applier process at the Independencia site, using Automated Label Applier E20172 equipment. Table 2 lists the product families in scope of this process.

Table 2 - Products Applicable to this Operational Qualification.

| Mod Code | Product Code or Product Family Identifier | Description |
| --- | --- | --- |
| 02 and 03 | 0012 | EZ Clean 2.5" Blade |
| 02 and 03 | 0012A | EZ Clean 2.75" Blade |
| 02 and 03 | 0012AM | EZ Clean 2.75" Modified Blade |
| 02 and 03 | 0014 | EZ Clean 6.5" Blade |
| 02 and 03 | 0014A | EZ Clean Blade, 4.0" |
| 02 and 03 | 0014AM | EZ Clean Modified Blade, 4.0" |
| 02 and 03 | 0014M | EZ Clean Modified Flat Blade, 6.5" |
| 02 and 03 | 0012M | EZ Clean 2.5" Modified Blade |
| 02 and 03 | 0013 | EZ Clean 2.75" Needle |
| 02 and 03 | 0013M | EZ Clean Modified Needle, 2.75" |
| 02 and 03 | 0118 | EZ Clean Sharp Needle, 2.0" |
| 02 and 03 | 0118A | EZ Clean Sharp Needle, 2.5" |

Table 3 lists all the equipment associated with the process under the scope of this study.

Table 3 - Equipment Applicable to this Operational Qualification.

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

# PREREQUISITES

The pre-requisites that were fulfilled prior to OQ execution are shown in Table 4.

Table 4 - Pre-Requisites

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification Completion Report | [Completion Report for Automated Label Applier E20172](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEerxNkdCinci-u_epipd-C0K%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC097511 Rev A |
| Software Validation Completion Report | Completion Report of Software Validation for Automated Label Applier E20172 | PRC097513 Rev A |
| Draft Procedures | Process Specification | PR001736 Draft |
| Draft Procedures | Control Plan | PR001754 Draft |
| Draft Procedures | I-Sheet | SPE004694 Draft |
| Draft Procedures | Bulk Packaging | TRP001934 Draft |
| Draft Procedures | Sales Unit Packaging | TRP001935 Draft |
| Draft Procedures | RSC Final Packaging | TRP001936 Draft |
| Draft Procedures | Loading of Components | TRP001937 Draft |
| Draft Procedures | Label Applying in Sales Unit Box | TRP001944 Draft |
| Draft Procedures | Packing area L-174 | TR011319 Draft |
| Draft Procedures | pFMEA | RMD001679 Draft |
| Drawing | Automated Label Applier | E20172 Rev A |

# Results and Discussion

The tests outlined in the protocol were performed per released test method. The results obtained showed that the Acceptance Criteria in the OQ protocol (PRC097514 Rev. A) were met.

The following OQ runs were performed:

Table 5 - OQ Process Parameter/Settings & Results

| Parameter Name | Product Code | Batch | Quantity Produced | Quantity Inspected | Process Parameter/Setting | Result |
| --- | --- | --- | --- | --- | --- | --- |
| OQ Low Process Setting | 030012 | 97514L | 100 | 100 | **60PSI** | Met |
| OQ Nominal Process Setting | 030012 | 97514N | 100 | 100 | **70PSI** | Met |
| OQ High Process Setting | 030012 | 97514H | 100 | 100 | **80PSI** | Met |

For the process setting, samples were run at each process setting and inspected for Material Specification Requirements (SPE004695 Rev Draft and MS00003 Rev BV). The summary of the results of this evaluation is listed below. The raw data and data analysis are located in the respective Attachments.

Table 6 - OQ Results Summary

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Requirement /Specification** | **Test Method** | **Data Type (Variable / Attribute)** | **Acceptance Criteria** | **Result [Pass/Fail/]** | **Location of Data** |
| Material Specification Requirements (SPE004695 & MS00003) | Visual Inspection | Variable  Attribute | 100 Acceptance Rate comparing against Specification with Zero (0) defects allowed. | PASS - For the OQ Batches | See Attachment 2 to 4 for FGQA results & Data Collection |
| Cosmetic | Visual Inspection | Variable  Attribute | No damage on the Printed box or label | PASS - For the OQ Batches |
| Legible | Visual Inspection | Variable  Attribute | Legible and correct information | PASS - For the OQ Batches |
| Integrity | Visual Inspection | Variable  Attribute | Uniform, firmly and securely attached to the Unit Box Pre-Printed | PASS - For the OQ Batches |
| Location | Visual Inspection | Variable  Attribute | Label location matches specified location in drawing | PASS - For the OQ Batches |

SV-Completion Report PRC097513 Rev A, mentions Maximo Work Order 10001990808 NUPROD for SRC003430 Rev A for equipment E20172 Maximo ID ES4457. This Work Order was Closed and should be in Progress Status.

# Operating Procedures

Manufacturing documents used during the execution of this protocol are documented as attachments on Supporting File section of Protocol PRC097514 Rev A. See table below for reference.

| No. | Attachment Title |
| --- | --- |
| 1 | Supporting File 1- I-sheet SPE004694 Draft |
| 2 | Supporting File 2 - Protocol Spanish version per WE0020 |
| 3 | Supporting File 3 – Process Specification PR001736 Draft |
| 4 | Supporting File 4 – Control Plan PR001754 Draft |
| 5 | Supporting File 5 – Set up Form FRM004256 Draft |
| 6 | Supporting File 6 – Bulk Packaging TRP001934 Draft |
| 7 | Supporting File 7 – Sales unit packaging TRP001935 Draft |
| 8 | Supporting File 8 – RSC Final Packaging TRP001936 Draft |
| 9 | Supporting File 9 – Loading of components TRP001937 Draft |
| 10 | Supporting File 10- PFMEA RMD001679 Draft |
| 11 | Supporting File 11- Material Specification SPE004695 Draft |
| 12 | Supporting File 12- I-sheet SPE004694 Draft ESP |
| 13 | Supporting File 13 – Process Specification PR001736 Draft ESP |
| 14 | Supporting File 14 – Control Plan PR001754 Draft ESP |
| 15 | Supporting File 15- Material Specification SPE004695 Draft ESP |
| 16 | Supporting File 16- Label Applying in Sales Unit Box TRP001944 Draft |
| 17 | Supporting File 17- FGQA Results |

# Deviations

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

# Product Disposition

Material used during Operational Qualification was disposed as scrap once validation was completed.

# Conclusions

As result of this testing activity, it is concluded that the Label Applier process has successfully passed OQ testing based on the acceptance criteria specified in OQ protocol PRC097514 Rev A. This OQ has established by objective evidence that the Automated Label Applier Process control limits and action levels can result in product that meets all predetermined requirements.

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

# attachments

**Attachment 1 – Training Record Form FM-0000809**

**Attachment 2 – FGQA Results Form FMWE0311.1 and Data Collection 97514L**

**Attachment 3 – FGQA Results Form FMWE0311.1 and Data Collection 97514N**

**Attachment 4 – FGQA Results Form FMWE0311.1 and Data Collection 97514H**

**Attachment 5 –** **97514L**

**Attachment 6 – 97514N**

**Attachment 7 – 97514H**