**Revision History for (PRC096186)**

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| **SUMMARY OF CHANGES** | |
| Revision No. | Description of Change |
| A | Original Document |
| B | Code 0012 & 0014 tested to cover the previous failures in batches from codes 0013 and 0014. |

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| --- | --- | --- | --- |
| **OPERATIONAL QUALIFICATION REPORT** | | | |
| Document Title: | Operational Qualification Report for Insulation Equipment Line 175 | | |
| Document Number / Revision: | PRC096186 Rev. B | | |
| 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/ MIMAS Line 175 | | |
| Product/Process: | Insulation and Pad Printing process for Megadyne blades Line 175 | | |
| Equipment: | E19590 Pad Printer Machine  Maximo ID ES3230  Maximo ID ES3257 | E19587 Heat Shrink Oven  Maximo ID ES3227 | E19585 & E19586  Heat Shrink Tubing Cutters  Maximo ID ES3225  Maximo ID ES3226 |
| OQ Protocol Reference: | PRC096184 Rev. B | | |
| N/A | | | |

# Document Approvals

Ethicon, Independencia

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# Executive Summary

The Operation Qualification (OQ) protocol PRC096184 Revision B has been completed for the equipment listed in Table 1 located at Independencia Plant, following the strategy laid out in the OQ protocol (PRC096184 Rev B).

The OQ acceptance criteria defined in PRC096184 Revision B were satisfactorily met for the 6 batches created, as summarized in Table 2. For all batches, the testing establishes that the process control limits, and action levels described in the operating procedure result in product that meets all predetermined requirements.

Table 1 - Equipment Information

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Equipment Description | Machine Number | Maximo ID Number | Source Code | Serial # | Supplier |
| Pad Printers with vision systems (small) | E19590  Rev A | ES3230 | SRC003327  Rev A | EE18280 | Prod Design |
| Pad Printers with vision systems (large) | E19590  Rev A | ES3257 | SRC003328  Rev A | EE18279 | Prod Design |
| Heat Shrink Oven | E19587  Rev A | ES3227 | SRC003333  Rev A | 195266 | Prod Design |
| Heat Shrink Tubing Cutters | E19585  Rev A | ES3225 | SRC003334  Rev A | E19585 | SAE Inc |
| Heat Shrink Tubing Cutters | E19586  Rev A | ES3226 | SRC003351  Rev A | E19586 | SAE Inc |

Table 2. Summary of the Heat Shrink and Pad Print Process OQ Testing

| Code | Requirement | Acceptance Criteria | Low  Parameter | Nominal Parameter | High Parameter | Result Pass / Fail |
| --- | --- | --- | --- | --- | --- | --- |
| 0012 | Heat Shrink | Zero defect for Class 0  Accept 12 / Reject 13 for Class III defect | PASS  0 rejects | PASS  0 rejects | PASS  0 rejects | PASS |
| 0014 | Pad Printing | Zero defect for Class 0  Accept 12 / Reject 13 for Class III defect | PASS  0 rejects | PASS  0 rejects | PASS  0 rejects | PASS |

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# Purpose

The report summarizes the Operational Qualification for the equipment listed in Table 1 located at Independencia Plant. PR-0000089 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 Heat Shrink and Pad Print processes result in product that meets all predetermined specifications per SPE004695 Rev Draft. Where acceptable objective evidence could not be provided, actions for failure resolution are documented.

# Scope & background

The scope of this Operational Qualification is limited to Pad Printers with Vision System E19590, Maximo ID ES3230 & ES3257, the Heat Shrink Oven E19587, Maximo ID ES3227 and Heat Shrink Tubing Cutters E19585 & E19586 Maximo ID ES3225 & ES3226 installed in production Line 175 for Megadyne process.

Failed Operational Qualification product codes from PRC096184 Rev A were successfully re-tested and validated using representative samples listed in Table 3.

Table 3 - Operational Qualification Materials

|  |  |  |
| --- | --- | --- |
| **Component** | **Description** | **Codes** |
| 6010011-01 | Subassembly, F/Blade, I/C 2.5 (0012) | 0012 |
| 6010011-04 | Subassembly, F/Blade, I/C 6.5 (0014) | 0014 |

Different batches were created for each setting parameter due to Megadyne production still being validated and transferring from Draper Utah to Ethicon Endo System. See Table 4 for the Operational Qualification batches.

Table 4 - Operational Qualification Batches

| **Component** | **Parameter** | **Batch** |
| --- | --- | --- |
| 0012 | Low | C0PML2 |
| Nominal | C0PMN2 |
| High | C0PMH2 |
|  | | |
| 0014 | Low | C0PML4 |
| Nominal | C0PMN4 |
| High | C0PMH4 |

Manufacturing Engineer and designee changed parameters on the equipment as per protocol for each process parameter setting (OQ Low, OQ Nominal and OQ High). See Table 5 for process setting parameters.

Table 5 - Process Setting Parameters

| Equipment | Parameter | OQ Run 1 Setting Low Parameters | OQ Run 2 Setting Nominal Parameters | OQ Run 3 Setting High Parameters |
| --- | --- | --- | --- | --- |
| Pad Printers with vision systems (small) | Air supply | 75.0 PSI | 80.0 PSI | 85.0 PSI |
| Pad Printers with vision systems (large) | Air supply | 75.0 PSI | 80.0 PSI | 85.0 PSI |
| Heat Shrink Oven | Temperature | 333 °F | 345 °F | 357°F |
| Tubing Cutter 1 | Air Supply | 75.0 PSI | 85.0 PSI | 95.0 PSI |
| Tubing Cutter 2 | Air Supply | 75.0 PSI | 85.0 PSI | 95.0 PSI |

According to the validation plan FB003341 Rev A, quantities established per PR-0000022 Rev. 11 (Franchise Procedure for Establishing Process Validation and Production Sampling Plans). Based on OQ quality requirements, the sample lot sizes were built as Table 6 states. Quality technician randomly inspected samples from each batch per SPE004695 Rev Draft and recorded the results in inspection data sheet FMWE0311.1. See Attachment #1 and #2.

Table 6 - Sampling Size

| Group | Parameter | Product Code | Samples |
| --- | --- | --- | --- |
| 1 | Low | 0012 | 10000 |
| 2 | 0014 | 10000 |
| 3 | Nominal | 0012 | 10000 |
| 4 | 0014 | 10000 |
| 5 | High | 0012 | 10000 |
| 6 | 0014 | 10000 |

# PREREQUISITES

The pre-requisites that must be fulfilled prior to OQ execution are shown below.

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification | Installation Qualification for Pad Printers with vision system Line 175 | PRC095097 Rev A |
| Installation Qualification Completion Report | Completion report of Installation Qualification for Pad Printers with Vision System Line 175 | PRC095098 Rev A |
| Installation Qualification | Installation Qualification Protocol for Heat Shrink Oven E19587 | PRC095225 Rev A |
| Installation Qualification Completion Report | Installation Qualification Protocol for Heat Shrink Oven E19587 Completion Report | PRC095232 Rev A |
| Installation Qualification | Installation Qualification Protocol for Heat Shrink Tubing Cutters E19585 & E19586 | PRC095222 Rev A |
| Installation Qualification Completion Report | Installation Qualification Protocol for Tubing Cutters E19585 & E19586 Completion Report | PRC095224 Rev A |
| Test Method Validation | Test Method validation for Megadyne electrodes presence vision system of Pad Printers E19590 Line 175. | PRC096182 Rev A |
| Test Method Validation Completion Report | Completion Report for Test Method Validation of Pad Printers with vision system E19590 | PRC096204 Rev A |
| Software Validation | Software Validation Protocol for Megadyne L175 Pad Printers with Vision System E19590 | PRC095254 Rev A |
| Software Validation Completion Report | Completion Report for E19590 Pad Printers with Vision System Software Validation Maximo ID ES3230 and ES3257 | PRC095255 Rev A |
| Software Validation | E19587 Heat shrink oven software validation Maximo ID ES3227 | PRC095422 Rev A |
| Software Validation Completion Report | Completion report for E19587 Heat shrink oven software validation Maximo ID ES3227 | PRC095423 Rev A |
| Software Validation | Software Validation for Tubing Cutter 1 E19585  Maximo ID ES3225 | PRC095631 Rev A |
| Software Validation Completion Report | Completion report for software validation for Tubing Cutter 1 E19585 Maximo ID ES3225 | PRC095632 Rev A |
| Software Validation | Software Validation for Tubing Cutter 2 E19586  Maximo ID ES3226 | PRC095703 Rev A |
| Software Validation Completion Report | Completion report for software validation for Tubing Cutter 2 E19586 Maximo ID ES3226 | PRC095792 Rev A |

# Results and Discussion

The tests outlined in the OQ protocol Revision B were performed per released test methods. The results obtained showed that the acceptance criteria in the OQ protocol (PRC096184 Rev B) were met for all batches. Table 2 outlines the Operational Qualification summary results

For the process settings, samples were run at each process settings and inspected for Material Specification Requirements (SPE004695 Rev Draft). The raw data and data analysis are in their respective attachments.

Revision B execution of the Operational Qualification protocol covers the failures occurred in the execution of Rev A. Code 0012 was substituted by code 0013 since these codes share the same process and have similar components. Code 0012 was tested for compliance with Heat Shrink visual inspection criteria and code 0014 for compliance with Pad Print visual inspection criteria.

The following OQ runs were performed:

**Heat Shrink Process:**

For Heat Shrink process, samples were run at each process setting and inspected for Material Specification Requirements (SPE004695 Rev Draft). Visual inspection, as shown in Table 10, successfully met the requirements per PRC096184 Rev B for code 0012. During execution of Operational Qualification protocol Revision A, code 0013 exhibited 29 class III defects when processed at the low parameter setting, this resulted in failing the batch. It was later determined that the Class III defects were caused by a dull tubing cutter blade and were not related to low parameter settings. With the blade issue corrected, results from code 0012 during Revision B demonstrate compliance with acceptance criteria for all parameter settings in Table 4 and covers the code 0013 failure from Revision A.

Table 10 – Heat Shrink Visual Inspection

| Code | Low Parameter | Nominal Parameter | High Parameter | Result |
| --- | --- | --- | --- | --- |
| 0012 | Pass | Pass | Pass | Pass |

**Pad Printing Process:**

For Pad Printing process, samples were run at each process setting in Table 4 and inspected for Material Specification Requirements (SPE004695 Rev Draft). Visual inspection, as shown in Table 11, successfully met the requirements per PRC096184 Rev B for code 0014. During execution of Operational Qualification Protocol Revision A, code 0014 exhibited 34 class III defects when processed at nominal parameter settings, this resulted in failing the batch. It was later determined that the Class III defects were caused by improper part holding during printing and were not related to nominal parameter settings. With the part holding issue corrected, results from code 0014 during Revision B, demonstrate compliance with acceptance criteria for all parameter settings in Table 4 and covers code 0014 failure in Revision A.

Table 11 – Pad Print Visual Inspection

| Code | Low Parameter | Nominal Parameter | High Parameter | Result |
| --- | --- | --- | --- | --- |
| 0014 | Pass | Pass | Pass | Pass |

# Operating Procedures

Manufacturing documents used during the execution of this protocol are documented as attachments in Supporting File section of Protocol PRC096184 Rev B. See table below for reference.

| **No.** | **Attachment Title** |
| --- | --- |
| 1 | Supporting File 1- TRP001928A Discharge of electrodes in the insulation area |
| 2 | Supporting File 2- TRP001931A Inspection of Electrodes in Insulation (paint defects) |
| 3 | Supporting File 3- TRP001926A Insulation cutting Machine |
| 4 | Supporting File 4- TRP001933A Electrodes Loading into Insulation Jig |
| 5 | Supporting File 5- TRP001932A Insulation Assy |
| 6 | Supporting File 6- TRP001927A Insulation Baking |
| 7 | Supporting File 7- TRP001929A Electrode inspection (Insulation) |
| 8 | Supporting File 8- TRP001925A Logo Printing |
| 9 | Supporting File 9- TRP001930A Inspection, cleaning and colocation of Cap |
| 10 | Supporting File 10- TR011321A Insulation area L-175 |
| 11 | Supporting File 11- Protocol Spanish version per WE0020 |
| 12 | Supporting File 12- Process Specification PR001720 Draft |
| 13 | Supporting File 13- Process Specification PR001720 Draft Spanish Version |
| 14 | Supporting File 14- Control Plan PR001754 Draft |
| 15 | Supporting File 15- Control Plan PR001754 Draft Spanish Version |
| 16 | Supporting File 16- Set up Form FRM004277 Draft |
| 17 | Supporting File 17- PFMEA RMD001679 Draft |
| 18 | Supporting File 18- Material Specification SPE004695 Draft |
| 19 | Supporting File 19- Material Specification SPE004695 Draft Spanish Version |
| 20 | Supporting File 20- I-sheet SPE004694 Draft |
| 21 | Supporting File 21- I-sheet SPE004694 Draft Spanish Version |

# Deviations

No deviations were found during the execution of Operational Qualification test cases (PRC096184 Rev B).

# Product Disposition

Products used during this Operational Qualification were disposed of as scrap after validation was completed.

# Conclusions

As a result of this testing activity, it is concluded that the Operational Qualification for the equipment listed in Table 1 and located in Line 175 has been successfully completed.

The NRs issued to address the defects found at the FGQA inspection for codes 0013 and 0014 during the execution of the Operational Qualification Revision A were satisfactory closed.

* NR-0148243 generated for the defect related to the distorted logo found in code 0014 in its nominal parameter
* NR-0148244 was generated for the tubing defect in code 0013 occurred in its lower parameter.

As a result of the NRs, the Operational Qualification Protocol PRC096184 Rev A failed, and after PRC096184 Rev B execution, it demonstrated satisfactory completion of the Operational Qualification.

# attachments

Attachment 1 Heat Shrink Visual Inspection

Attachment 2 Pad Print Visual Inspection

Attachment 3 Training Record Form FM-0000809

Attachment 4 Set Up Form

Attachment 5 Form FMWE0348.4X