**Revision History for (PRC096184)**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **OPERATIONAL QUALIFICATION PROTOCOL** | | | |
| Document Title: | Operational Qualification Protocol for insulation equipment Line 175 | | |
| Document Number / Revision: | PRC096184 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 | | |
| 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 |
| Validation Assessment Reference: | Transfer of Megadyne electrodes manufacturing process to Ethicon Independencia / DC003495 | | |
| Operational Qualification to validate together the E19590 Pad Printer with vision system inspection, E19587 Heat Shrink Oven, and the Heat Shrink Tubing Cutters E19585 & E19586 for Megadyne electrodes in Line 175. | | | |

# Document Approvals

Ethicon, Independencia

| Function | Name | Signature | Date |
| --- | --- | --- | --- |
| **Originator** | Ivan Armenta | E-sig in Epicenter | Electronic Date in Epicenter |
| Lifecycle Quality Engineer | Ihsan Samara | E-sig in Epicenter | Electronic Date in Epicenter |
| Plant Quality Systems Engineer | Victor Cantu | E-sig in Epicenter | Electronic Date in Epicenter |
| Plant MEST Manager | Gabriel Herrera | E-sig in Epicenter | Electronic Date in Epicenter |
| Business Unit Manager | Izza Rodriguez | E-sig in Epicenter | Electronic Date in Epicenter |
| Planning | Marisol Vazquez | E-sig in Epicenter | Electronic Date in Epicenter |
| Plant QS Manager | Francisco Del Val | E-sig in Epicenter | Electronic Date in Epicenter |
| LCE Design Engineer | Brian Walter | E-sig in Epicenter | Electronic Date in Epicenter |
| Approver | Luis Gutierrez | E-sig in Epicenter | Electronic Date in Epicenter |

# Purpose

The protocol outlines the Operational Qualification for the Pad Printers with vision system E19590, Maximo ID ES3230 and ES3257 and the Heat Shrink Oven E19587, Maximo ID ES3227 and Heat Shrink Tubing Cutters E19585 & E19586 Maximo ID ES3225 and ES3226 located at manufacturing Line 175 for Megadyne electrodes, in Ethicon, Independencia. Street Durango #2751. Cd. Juarez, Chihuahua, Mexico. PR-0000089 Franchise Procedure for Validation (Shared) defines the requirements & approach for Operational Qualification.

The purpose of revision B of the Operational Qualification is to demonstrate and document that the Pad Printers with vision system E19590, Maximo ID ES3230 and ES3257 and the Heat Shrink Oven E19587, Maximo ID ES3227 and Heat Shrink Tubing Cutters E19585 & E19586 Maximo ID ES3225 and ES3226 for Megadyne electrodes in Line 175, operate as intended and meet all predetermined specifications. This is an initial and full Operational Qualification of the insulation assembly and pad printing processes.

Revision B of the Operational Qualification protocol will repeat and cover the failures which occurred in the execution of Rev A. Although the failures occurred in codes 0013 and 0014, due to material availability, product code 0012 will be substituted for code 0013 since these codes share the same process and have similar components. Code 0012 in Revision B will be tested for compliance with Heat Shrink visual inspection criteria and code 0014 will be tested for compliance with Pad Print visual inspection criteria.

# Scope & Background

The scope of this Operational Qualification is limited to Pad Printers with vision system E19590, Maximo ID ES3230 and ES3257 and 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.

## Equipment, gages, tooling and fixtures to be used on this protocol will be referenced in this document under Process Specification PR001720 Rev. Draft.

Equipment under OQ will operate under parameters listed on PR001720 of Rev Draft and Set Up FRM004277 Rev Draft.

Operational Qualification product codes will be validated with representative samples such as Flat Blades and Needle configurations referenced in section 9. Modified Blades and Modified Standard Needles will be validated in a separate engineering study.

All activities of this protocol are limited to the product codes listed in Table 1.

Table 1 - Operational Qualification Product Codes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Applicable Product Codes | | | | |
| 0012 | 0012A | 0012MBN | 0014 | 0014A |
| 0014AM | 0014M | 0012BN5 | 0012ABN | 0012M |
| 0014BN | 0012AMBN | 0013 | 0013M | 0118 |
| 0118A | C012ABN | 0012AM |

All equipment associated with the processes under the scope of this Operational Qualification are listed in Table 2.

Table 2 - 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 |

# 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

## Protocol Execution: Originator or designee.

## Visual Inspections: Finished Good Quality Assurance or Technician Quality Systems Technician.

## Integrity Test: Finished Good Quality Assurance Technician

## Defect Classification: Quality Engineer and/or SME

## Machine Operation: Maintenance Technician or designee.

## Completion Report: Originator or designee.

# Pre-requisites

All the Installation Qualification activities pertaining to every piece of equipment, tooling, gages, shall be completed and released in the applicable PLM system before OQ execution.

Associates who manufacture product or perform inspections for this OQ must be trained/qualified prior to initiation of this protocol. The training objective evidence must be attached to either the executed protocol or the report document.

This document must be fully approved and released in applicable PLM system before its execution

Test, Measurement & Inspection Methods to be used for execution of OQ testing must be assessed per PR800-002 Franchise Procedure for Test Method Validation (Shared), completed and released prior execution of this OQ.

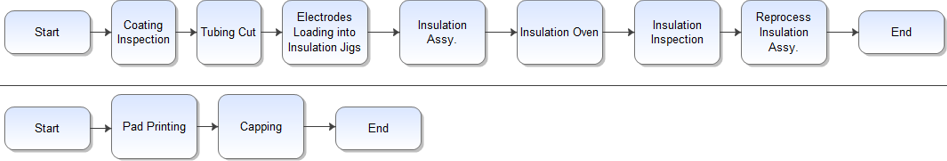
The pre-requisites that must be fulfilled prior to OQ execution are shown in Table 3.

Table 3 - OQ Pre-Requisites

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification | Installation Qualification for Pad Printers with vision system Line 175 | PRC095097 Rev A |
| Operational Qualification Report | Operational Qualification for Insulation Equipment Line 175 | PRC096186  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 |

# Manufacturing Process Flow

## The Megadyne validation plan FB003341Rev A provides step-by-step instructions for processes performed using Pad Printers with vision system E19590, Maximo ID ES3230 and ES3257 and the Heat Shrink Oven E19587, Maximo ID ES3227 and Heat Shrink Tubing Cutters E19585 & E19586 Maximo ID ES3225 and ES3226.



## Insulation Process

* Coating Inspection.
  + 100% inspect electrodes for the appearance of straightness and coating defects.
* Tubing Cut.
  + Determine proper insulation material and cut length for electrodes to be insulated.
  + Cut insulation to specified length using Tubing Cutters.
* Electrode loading into insulation jigs.
  + Load coated electrodes into insulation jigs.
* Insulation Assy.
  + Slide cut insulation lengths onto the electrode loaded in the insulation jigs.
* Insulation Oven.
  + Heat shrink of insulation on the electrodes.
* Part cool and unload
  + Once cool, remove insulated electrodes from fixtures
* Insulation inspection
  + 100% inspect electrodes for distal and proximal insulation exposures.
* Reprocess insulation assy.
  + Reprocess insulation assembly if product is not conforming according to the insulation criteria.
* Pad Printing.
  + This operation consists in the logo printing on the electrode.
* Capping.
  + This operation consists in 100% visual inspection of the logo printing and placement of cap for every conforming electrode.

## Assembly manual training operation for Megadyne Line 175

* Main assembly training manual
  + TR011321A Insulation area L-175
* Manual training operations for Megadyne Line 175
  + TRP001928A Discharge of electrodes in the insulation area
  + TRP001931A Inspection of Electrodes in Insulation (paint defects)
  + TRP001926A Insulation cutting Machine
  + TRP001933A Electrodes Loading into Insulation Jig
  + TRP001932A Insulation Assy
  + TRP001927A Insulation Baking.
  + TRP001929A Electrode inspection (Insulation).
  + TRP001925A Logo Printing
  + TRP001930A Inspection, cleaning and colocation of Cap

# Process Parameters

Equipment Pad Printers with vision system E19590 (Maximo ID ES3230 and ES3257), Heat Shrink Oven E19587 (Maximo ID ES3227) and Heat Shrink Tubing Cutters E19585 & E19586 (Maximo ID ES3225 and ES3226) parameters are listed on Table 4.

Parameters used for this protocol will be categorized as HIGH, NOMINAL and LOW values where applicable. Process parameters are as per Process Specification in PR001720 Rev Draft.

## Process Parameters / Inputs

Table 4 - Equipment parameters

|  |  |  |
| --- | --- | --- |
| **Process Step** | **Parameter** | ***Range or Setting to be Validated*** |
| Tubing Cut | Pressure (PSI) | 85 ± 10 psi |
| Heat Shrink | Temperatures (°F) | 345 ± 12 °F |
| Pad Printing | Pressure (PSI) | 80 ± 5 psi |

Parameters such as Time, will remain as a constant parameter in the Heat Shrink Oven as this parameter is established by the PLC system. Soaking time for all recipes is 30 min. Additional cooling time is added as a safety measure for associates. Cooling time varies based on the established safety temperature that is 130 °F.

## Other Critical Process Inputs and Controls Required

N/A

# Components Assessment

Components/materials to be utilized during the execution of this operational qualification will be referenced in the Bill of Materials of product codes stated in Table 1. For the accurate mix of product codes to be run under this document, refer to section 14.

All components/material used in this protocol will be received by Megadyne and previously inspected and Certificated by Megadyne RMI in Draper UT.

The materials/components that will be utilized for the Operational Qualification are listed on Table 5 below.

Table 5 - Operational Qualification Materials

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

The above components serve as representative samples for the failed Flat Blade and Needle configurations from Rev. A testing. The combination of Rev. A and B activities covers all 18 Codes mentioned on Table 1 except modified needles and blades. See Megadyne validation plan FB003341 Rev A section 7.0 Validation Strategy for further details.

Revision B of the Operational Qualification protocol will repeat and cover the failures occurred in the execution of Rev A. Although the failures occurred in batches from codes 0013 and 0014, due to material availability, code 0012 will be used as a replacement for code 0013 since these codes share the same process and have similar components. New code 0014 electrodes will be used to repeat failed pad print testing from Rev. A. Codes 0012, 0012BN5 and 0118A were previously validated in Operational Qualification PRC096184 Revision A.

Additional details such as lot/batch number and expiration date (if applicable, insulation and ink used) will be included in the OQ report.

# Operating Procedures

## The Manufacturing Procedure, PR001720 Rev Draft, provides instructions on the processes performed on Megadyne electrodes Line 175. See section 7.3 for the manufacturing procedures of Line 175.

# Training Requirements

## Training is required for all operators, mechanics, technicians, engineers, and other personnel associated with running the protocol except the originator and approvers. See section 7.3.

## Training will be conducted by the protocol originator or designee and will consist of performing a review of this Operational Qualification Protocol (PRC096184) and its requirements.

## Training will be documented using form FM-0000809. The completed hard copies of the forms will be provided to the training department to be entered into the Compliance Wire system and one copy will be attached to the Completion Report PRC096186 Rev A.

# Requirements and Acceptance Criteria / CTQ List

## Requirements and acceptance criteria are listed in Table 6 below.

Table 6 – Acceptance Criteria

| Attribute | Test Method | Specification | Acceptance Criteria |
| --- | --- | --- | --- |
| Heat Shrink | SPE004695 | Wrong, missing or misassembled / damaged heat shrink tubing / PTFE tubing. Wrong location or incomplete recovery. | Zero defect for Class 0 requirement with heat shrink  Accept 12 / Reject 13 for Class III defect with heat shrink. |
| Pad Printing | SPE004695 | The logo (marketed name of device or trademark) on device is incorrect, missing, illegible, or damaged | Zero defect for Class 0 requirement for Pad Print  Accept 12 / Reject 13 for Class III defect with Pad Print. |

# Worst Case Condition Assessment

## The purpose of this protocol is to verify that the equipment/system operates as designed and is capable across the defined operating range. Each parameter identified in the Process Parameters section will be tested at worst case conditions; each batch for the OQ portion of this protocol will be set with the extreme (low and high) as well as nominal values of the setup parameters per Process Specification PR001720 Rev Draft.

## Worst case process setting conditions for equipment Pad Printers with vision system E19590, Maximo ID ES3230 and ES3257 and the Heat Shrink Oven E19587, Maximo ID ES3227 parameters are listed in Table 7.

**Table 7- Worst-Case Description**

|  |  |  |
| --- | --- | --- |
| **Process** | **Low Process Setting** | **High Process Setting** |
| Tubing Cutter Pressure (PSI) | 75.0 PSI | 95.0 PSI |
| Heat Shrink Temperature (°F) | 333 °F | 357 °F |
| Pad Printing Pressure (PSI) | 75.0 PSI | 85.0 PSI |

# OQ Test Plan

## Obtain all required material per Table 5 using BOMs for each subassembly part number.

## Manufacturing Engineer or designee will change parameters on the equipment for each process parameter settings (OQ Low, OQ Nominal and OQ High). See Table 9 for process setting parameters.

## Different batches will be created for each setting parameter due to Megadyne production still being validated and transferring from Draper Utah to Ethicon Endo system. See Table 8 for the Operational Qualification batches.

Table 8- Operational Qualification Batches

| **Component** | **Parameter** | **Batch** | **Heat shrink visual inspection** | **Pad Printing visual inspection** |
| --- | --- | --- | --- | --- |
| 0012 | Low | C0PML2 | Zero defect class 0  Accept 12 / Reject 13 for Class III defect | N/A |
| Nominal | C0PMN2 | Zero defect class 0  Accept 12 / Reject 13 for Class III defect | N/A |
| High | C0PMH2 | Zero defect class 0  Accept 12 / Reject 13 for Class III defect | N/A |
| 0014 | Low | C0PML4 | N/A | Zero defect class 0  Accept 12 / Reject 13 for Class III defect |
| Nominal | C0PMN4 | N/A | Zero defect class 0  Accept 12 / Reject 13 for Class III defect |
| High | C0PMH4 | N/A | Zero defect class 0  Accept 12 / Reject 13 for Class III defect |

Table 9 - 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 |

## Attribute testing for heat shrink and printing defects will be performed by the Quality Technician using the sample size shown in Table 10 to comply with the operational testing.

## Quality technician will visually inspect samples per SPE004695 Rev Draft and record results on inspection data sheet FMWE0311.1. Do not tear down or destroy samples for this inspection.

## Quality Engineer and SME will review rejected samples to determine classification of defect.

## Batches built under OQ strategy will be inspected at the minimum sample requirement of 299 per CP0030. This will provide at least 99% reliability at 95% confidence interval with no class 0 or class I functional non-conformances. A sample size of 299 pieces is required to adequately perform testing for attribute data. The sample size is based on the BINOMIAL DISTRIBUTION (as defined below) assuming 99% reliability at a 95% confidence and with an acceptance number c = 0 for class 0 and class I defects.



## Performance (Reliability) requirements are as established in CP0198 and CP0030. Based on a minimum sample size of 299, the criteria for success are as follows:

### Greater than 99% probability at 95% confidence interval with no class 0 defects.

### At least 99% probability at 95% confidence interval with no class I defects.

### At least 97.5% probability at 95% confidence interval with no more than two (2) class II defects. (Using a sample size of 299 as defined per section 7.5.2, two (2) class II defects are allowable and will provide a reliability exceeding 97.5% at 95% confidence.)

### At least 93.5% probability at 95% confidence interval with no more than twelve (12) class III functional defects. (Using a sample size of 299 as defined per section 7.5.2, twelve (12) class III defects are allowable and will provide a reliability exceeding 93.5% at 95% confidence.)

## The above reliability must be demonstrated for each product code individually. Quality technician will document inspections in the F.G.Q.Q OQ/ PQ audit sheet.

## Any instrument failure or non-conformance per Material Specification SPE004695 Rev Draft that is not related to the manufacturing process equipment parameters will not affect the criteria for success. However, analysis and corrective action must be documented under a Nonconformances in ETQ System per 100254122 Rev. 16. If the root cause for any non-conformance at FGQA exceeding AQL requirements is related to the equipment parameter being qualified and validated under this protocol, a corrective action will be documented and implemented in the form of an addendum. Addendum must be approved by the individuals listed on the signature page and the Plant Quality Manager prior to restarting the protocol or specification of the protocol.

## The high, low and nominal parameter of each equipment will be set per Process specification PR001720 Rev Draft.

# Sampling Plan and Rationale

## 100% in-process visual inspection for tubing cutters (folded, wrong length, damaged tubing), heat shrink (damaged, misplaced, incomplete recovery or wrong tubing) and pad printing (logo is present and legible) will be performed by the line associates on the total quantity that will be produced.

* 1. This validation is intended to qualify appropriate Tubing Cut, Heat Shrink, and Pad Printing performance of the equipment listed in Table 2 for product codes listed in Table 1.
  2. Each activity will be performed and documented by trained associates in the process for Line 175. See section 7.4.
  3. 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 size will be as the Table 10 states.
  4. The “Accept/Reject Numbers” listed below are calculated using the Binomial Distribution function shown above and the AQL’s stated in CP0030, section 4.1.6 for class II and III defects. The calculation for acceptance number “c” assumes 100% inspection, a sample size of n = 299 and probability of acceptance of 95% for AQL. The reject number is defined as one number higher than the accept number. Please note the AQL listed below based on CP0030, section 4.1.6 and the “Accept/Reject” numbers truncated to the lower whole number.

Table 10 - Sampling size

| Group | Parameter | Product Code | Build Qty Samples | Inspect Qty Samples |
| --- | --- | --- | --- | --- |
| 1 | Low | 0012 | 10000 | 299 |
| 2 | Nominal | 10000 | 299 |
| 3 | High | 10000 | 299 |
| 4 | Low | 0014 | 10000 | 299 |
| 5 | Nominal | 10000 | 299 |
| 6 | High | 10000 | 299 |

**Table 11: Acceptance Criteria**

|  |  |  |
| --- | --- | --- |
| Nonconformity Classification | Accept/Reject Numbers | Minimum required process performance |
| 0 | 0/1 | > 0.99 @ 95% confidence |
| I | 0/1 | 0.99 @ 95% confidence |
| II | 2/3 | 0.975 @ 95% confidence |
| III | 12/13 | 0.935 @ 95% confidence |

* 1. Attribute testing for heat shrink and pad printing defects will be performed by the Quality Technician using the sample size shown in Table 10 and documented in data sheet FMWE0311.1.
  2. If the Criteria for Success are not met for this protocol, or any portion of this protocol, root cause and corrective action will be identified, implemented and documented under the completion report and under the appropriates quality systems.
  3. In case there is a defect/rejection related with the changes addressed under this document, this protocol will fail.
  4. Defects not related to the execution of this protocol will be recorded as observational data but will not affect the outcome of the test.

# Material Disposition

Product used during this Operational Qualification will be sent to Scrap and some of the material will be used for engineering tests. All raw material will be labelled as “experimental” and final product will contain the “not for human use” label attached to their carts until Protocol finish.

# Deviation Handling

## If any deviation is identified during the execution of this protocol, it will be documented in the completion report PRC096186 using Validation Deviation Form 100646188.

# Reference Documents

The following documents are used to develop, to support, or are referenced within this Operational Qualification Protocol.

| Document Number | Document Title | Revision |
| --- | --- | --- |
| PRC095097 | Installation Qualification for Pad Printers with Vision System Line 175 | A |
| PRC095254 | Software Validation Protocol for Megadyne L175 Pad Printers with Vision System E19590 | A |
| PRC095225 | Installation Qualification Protocol for Heat Shrink Oven E19587 | A |
| PRC095422 | E19587 Heat shrink oven software validation Maximo ID ES3227 | A |
| PRC095222 | Installation Qualification Protocol for Heat Shrink Tubing Cutters E19585 & E19586 | A |
| PRC095631 | Software Validation for Tubing Cutter 1 E19585 Maximo ID ES3225 | A |
| PRC095703 | Software Validation for Tubing Cutter 2 E19586 Maximo ID ES3226 | A |
| PRC094976 | Mimas Non-Coating Equipment Criticality Assessment | C |
| PR-0000089 | Franchise Procedure for Validation (Shared) | 14 |
| 100650854 | Franchise Procedure for Test Method Validation (Shared) | 3 |
| E19590 | Pad Printers with vision systems | A |
| E19587 | Heat Shrink Oven | A |
| E19586 | Heat Shrink Tubing Cutter 2 | A |
| E19585 | Heat Shrink Tubing Cutter 1 | A |
| FMWE0419.10 | Attribute Gage Control - Screening Method | G |
| SPE004695 | Material Specification for Megadyne E-Z CLEAN Electrosurgical Electrodes | Draft |
| DC003495 | Transfer of Megadyne electrodes manufacturing process to Ethicon Independencia | Draft |
| FB003341 | Megadyne Validation Plan | A |
| ENG-PRT-106 | Test Protocol, Insulation Bond Strength (Megadyne) | A |

# Attachments

The following are appendices to this document.

| No. | Attachment Title |
| --- | --- |
| 1 | FGQA results |
| 2 | Supporting File 1- TRP001928A Discharge of electrodes in the insulation area |
| 3 | Supporting File 2- TRP001931A Inspection of Electrodes in Insulation (paint defects) |
| 4 | Supporting File 3- TRP001926A Insulation cutting Machine |
| 5 | Supporting File 4- TRP001933A Electrodes Loading into Insulation Jig |
| 6 | Supporting File 5- TRP001932A Insulation Assy |
| 7 | Supporting File 6- TRP001927A Insulation Baking |
| 8 | Supporting File 7- TRP001929A Electrode inspection (Insulation) |
| 9 | Supporting File 8- TRP001925A Logo Printing |
| 10 | Supporting File 9- TRP001930A Inspection, cleaning and colocation of Cap |
| 11 | Supporting File 10- TR011321A Insulation area L-175 |
| 12 | Supporting File 11- Protocol Spanish version per WE0020 |
| 13 | Supporting File 12- Process Specification PR001720 Draft |
| 14 | Supporting File 13- Process Specification PR001720 Draft Spanish Version |
| 15 | Supporting File 14- Control Plan PR001754 Draft |
| 16 | Supporting File 15- Control Plan PR001754 Draft Spanish Version |
| 17 | Supporting File 16- Set up Form FRM004277 Draft |
| 18 | Supporting File 17- PFMEA RMD001679 Draft |
| 19 | Supporting File 18- Material Specification SPE004695 Draft |
| 20 | Supporting File 19- Material Specification SPE004695 Draft Spanish Version |
| 21 | Supporting File 20- I-sheet SPE004694 Draft |
| 23 | Supporting File 21- I-sheet SPE004694 Draft Spanish Version |

# APENDIX 1 – FGQA results

