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| --- | --- |
| **PERFORMANCE QUALIFICATION PROTOCOL** | |
| Document Title: | Performance Qualification for Megadyne Phase 1 |
| Document Number / Revision: | PRC096295 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 |
| Product/Process: | Megadyne Electrodes |
| Equipment: | See Table 3 |
| Validation Assessment Reference: | DOC027653 Rev A  FB003341 Rev A |
| N/A | |

**Revision History for (PRC096295)**

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

# Document Approvals

The protocol 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** | Ricardo Miranda | Electronic Signature in PLM System | Electronic Date in PLM System |
| Lifecycle Quality Engineer | Ihsan Samara | Electronic Signature in PLM System | Electronic Date in PLM System |
| Franchise Package Development Engineer | Matthew Varga | Electronic Signature in PLM System | Electronic Date in PLM System |
| Plant Quality System Engineer | Victor Cantu | Electronic Signature in PLM System | Electronic Date in PLM System |
| Plant MEST Manager | Gabriel Herrera | Electronic Signature in PLM System | Electronic Date in PLM System |
| Business Unit Manager | Izza Rodriguez | Electronic Signature in PLM System | Electronic Date in PLM System |
| Planning | Marisol Vazquez | Electronic Signature in PLM System | Electronic Date in PLM System |
| Franchise Sterilization Sciences | Ravi Patel | Electronic Signature in PLM System | Electronic Date in PLM System |
| Plant QS Manager | Francisco Del Val | Electronic Signature in PLM System | Electronic Date in PLM System |
| Lifecycle Design Engineer | Brian Walter | Electronic Signature in PLM System | Electronic Date in PLM System |
| Approver | Luis Gutierrez | Electronic Signature in PLM System | Electronic Date in PLM System |

# PURPOSE

The protocol outlines the Performance Qualification requirements for the entire manufacturing/packaging process for Megadyne Electrodes located at Independencia Plant. PR-0000089 Rev 14 Franchise Procedure for Validation (Shared) defines the requirements & approach for Performance Qualification.

The purpose of this Performance Qualification is to establish by objective evidence that:

* The PTFE coating, insulation and packaging processes in lines 173, 174 and 175 consistently produce a product that meets all predetermined requirements of section 8 and establishes confidence that the process is effective and reproducible.
* Process control limits and action levels for all equipment listed in Table 3 results in a product that meets all predetermined specifications SPE004695 Rev Draft and MS00003 BW Draft (Only for packaging).
* This is an initial and full Performance Qualification of the manufacturing process to enable transfer of the first 18 electrodes product codes from Draper to Juarez. This validation will be performed in parallel to the existing manufacturing/packaging processes in Draper, Utah.

# SCOPE AND BACKGROUND

The scope of this Performance Qualification study includes the PTFE coating, insulation, pad printing, capping and packaging processes (lines 173, 174 and 175), using the equipment listed in Table 3. Table 1 lists the product codes in scope of this process qualification.

Table - Products Applicable to this Performance Qualification.

| Product Code | Description |
| --- | --- |
| 0012 | EZ Clean 2.5" Blade |
| 0012A | EZ Clean 2.75" Blade |
| 0012AM | EZ Clean 2.75" Modified Blade |
| 0012MBN | EZ Clean Modified Flat Blade, BNS, 2.5" |
| 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" |
| 0012BN5 | EZ Clean Flat Blade, BNS, 2.5" (Quantity 500) |
| 0012ABN | EZ Clean Flat Blade, BNS, 2.75" (Quantity 100) |
| 0012M | EZ Clean 2.5" Modified Blade |
| 0014BN | EZ Clean Flat Blade, BNS, 6.5" |
| 0012AMBN | EZ Clean, Modified Blade, BNS, 2.75" |
| 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" |
| C012ABN | EZ Clean, 2.75", Custom Exposure, BNS (QTY 100) |

The product codes listed in Table 2 below will be used as representative samples for the execution of this protocol. These product codes will represent the two tip profiles in scope of this protocol and undergo the complete assembly process, including normal and bulk packaging.

Table 2 – Product Codes

| Product Code | Description |
| --- | --- |
| 0012 | EZ Clean 2.5" Blade |
| 0014 | EZ Clean 6.5" Blade |
| 0012BN5 | EZ Clean Flat Blade, BNS, 2.5" (Quantity 500) |
| 0012M | EZ Clean 2.5" Modified Blade |
| 0013 | EZ Clean 2.75" Needle |
| 0118A | EZ Clean Sharp Needle, 2.5" |

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

Table 3 - Equipment Applicable to this Performance Qualification.

| **Process/Line** | **Equipment Description** | **Machine Number** | **Maximo ID Number** | **Serial #** | **Supplier** |
| --- | --- | --- | --- | --- | --- |
| PTFE Coating/ Line 173 | Coating Burn-Off Oven | E19584 | ES3224 | 195267 | Despatch |
| Manual Sandblaster | E19574 | ES3214 | Z59390 | Clemco/Zero |
| Automated sandblaster | E19575 | ES3215 | PROD-19155A | PROD Design |
| Blades coating process fixtures | T02737 | n/a | n/a | n/a |
| Blades coating loading fixture | T02774 | n/a | n/a | n/a |
| Blades loading box fixture 2.75" | T02776 | n/a | n/a | n/a |
| Blades loading box fixture 4.00" | T02781 | n/a | n/a | n/a |
| Blades loading box fixture 6.50" | T02782 | n/a | n/a | n/a |
| Blades guiding fixture | T02777 | n/a | n/a | n/a |
| Paint Refrigerator | E19576 | ES3216 | T85167J19 | Traulssen |
| Paint Roller drum mixer | E19577 | ES3217 | CZ-20018 | U.S. Stoneware |
| Paint Roller drum mixer | E19577 | ES4324 | CZ-20017 | U.S. Stoneware |
| Paint Roller drum mixer | E19577 | ES4325 | CZ-20019 | U.S. Stoneware |
| Coating Modifier Scale | E20258 | EE4195 | 6A4456124 | AND |
| Pre Heat oven | E19578 | ES3218 | 195291 | Despatch |
| Manual Paint Spray Gun | E19580 | ES3220 | n/a | Graco |
| Rotary stand fixture | T02738 | ES2909 | n/a | n/a |
| Paint Booth w/NESHAP Filtration | E19579 | ES3219 | n/a | Col-Met |
| Ultrasonic Cleaner | E20012 | ES4002 | S1000029826 | Elma |
| Ionizer Air Gun | E19699 | ES2907 | 20084006517011937 | Simco |
| Curing oven w/truck | E19582 | ES3222 | 195289 | Despatch |
| Oven Humidifier | E19583 | ES3223 | RDU-19-22593 | Herrmidifirst Co |
| Drying Room HVAC | E20094 | ES4035 | 0120-47324-C.1.3 | Northern Air Systems Inc |
| Drying Room Humidifier | E20130 | ES3393 | MF20-5875 | Herrmidifirst Co |
| Drying Room Humidifier | E20130 | ES4001 | MF20-5876 | Herrmidifirst Co |
| Water Filtration System | E20189 | ES4327 | MC-RODI -400UHE-20 | Spectra Pure |
| Process Timer | n/a | EE4421 | n/a | WUTL |
| Process Timer | n/a | EE4422 | n/a | WUTL |
| Insulation/ Line 175 | Pad Printers with vision systems (small) | E19590 | ES3230 | EE18280 | Prod Design |
| Pad Printers with vision systems (large) | E19590 | ES3257 | EE18279 | Prod Design |
| Heat Shrink Oven | E19587 | ES3227 | 195266 | Prod Design |
| Heat Shrink Tubing Cutters | E19585 | ES3225 | E19585 | SAE Inc |
| Heat Shrink Tubing Cutters | E19586 | ES3226 | E19586 | SAE Inc |
| Insulation Fixture | T02789 | n/a | n/a | Fisher Precision |
| Packaging/ Line 174 | Multivac Sealer with in-line printer | E19592 | ES3232 | 277288 | Multivac |
| Dust Collector | E20125 | ES3228 | n/a | SIMCO |
| Chiller | E20126 | ES3213 | n/a | Dimplex Thermal Solutions |
| Tooling 12x1 | T02769 | ES3221 | n/a | Multivac |
| Tooling 12x2 | T02770 | ES4036 | n/a | Multivac |
| Tooling Trolley | E20127 | ES4037 | n/a | Multivac |
| Automated Label Applier | E20172 | ES2911 | PROD-19341A | PROD Design |
| Smart Conveyor with scale system | E19594 | ES3234 | PROD-19210A | PROD Design |
| Label Dispenser | E20128 | ES4038 | L10644FS | START |
| Zebra Printer | E20129 | ES4039 | 76J190200515 | ZEBRA |
| Label Dispenser | E20128 | ES4040 | L10642FS | START |
| Zebra Printer | E20129 | ES4041 | 76J190200533 | ZEBRA |
| Pack Out Equipment with Scale System | E20132 | ES4042 | PROD-19253A | PROD Design |
| Zebra Printer | E20129 | ES4043 | 76J184200703 | ZEBRA |
| Bulk Packaging Smart System | E20295 | ES4377 | N/A | PROD Design |
| Bulk Packaging Weight Scale | E20296 | ES4378 | N/A | PROD Design |
| Automated Label Applier | E20172 | ES4457 | PROD-20145A | PROD Design |

# DEFINITIONS, TERMS AND ABBREVIATIONS

Refer to 100632965 Rev 3 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

## Raw Material: Component Engineer or designee

* Prepare kit of component per lot considering approx. 30% scrap rate
* Record the Material used per Lot

## Protocol Execution: Originator or designee.

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

## Packaging Visual Inspections: Finished Good Quality Assurance Technician or designee.

## Defect Classification: Quality Engineer and/or SME.

## Machine Operation: Maintenance Technician or designee.

## Completion Report (Documentation of Test Results): Originator or designee

## Training: Originator or designee

## Device Assembly: Associates

## Set Up: Mechanic or designee

* Correct Electrical Pneumatic Hookup
* Equipment Stable and Secure
* Correct Tooling
* Tooling Identification
* Setup Procedures
* PM
* Calibration

# PRE-REQUISITES

The pre-requisites that must be fulfilled prior to PQ execution are shown below for each process:

* Ensure protocol PRC096295 Rev A is approved before execution.
* Ensure all personnel required for execution is trained before execution.
* Ensure the TR’s are available for each manufacturing station prior to the line’s training and start of the line’s build.
* Ensure all IQ/OQ/SV activities have been completed prior to start.
* Raw material for this protocol will be inspected by Megadyne Draper UT, the material used in this protocol will not be inspected by INDEPENDENCIA site for RMI.

The following Tables (4, 5 and 6) list all the pre-requisite documents necessary for the execution of each portion of this protocol.

1. Coating PTFE Line 175

The Coating portion of this Performance Qualification can be executed once all the pre-requisites listed for Coating process have been approved and released.

Table 4 - Pre-Requisites for Coating PTFE

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification – CR | [IQ CR for Coating Burn-Off Oven E19584/Coating Burn-Off Oven Extractor E19588](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgBjOQiCinci-u_epipd-HUK%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC095456 Rev A |
| Installation Qualification – CR | [IQ CR Equipment for Sandblasting Area](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgAwUZeCinci-u_epipd-HUm%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC095481 Rev A |
| Installation Qualification – CR | CR for Coating Area | PRC096087 Rev A |
| Installation Qualification – CR | [Completion Report the Ultrasonic Cleaner.](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEfgqNbiCinci-u_epipd-D0E%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC095994 Rev A |
| Installation Qualification – CR | [CR for Drying](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEdAn5fjCinci-u_epipd-BNR%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) Room | PRC096203 Rev A |
| Installation Qualification – CR | CR for Curing oven w/Truck E19582, Oven Humidifier E19583, Curing Ovens Extractor E19581, T02737 Blades co | PRC096664 Rev A |
| Software Validation – CR | [Software Validation Completion Report for Megadyne L173 E19578 Pre-Heat Oven ES3218](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgtvjofCinci-u_epipd-Hfu%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC096338 Rev A |
| Software Validation – CR | [Completion Report for E19584 Coating Burn-Off Oven software validation Maximo ID ES3224](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgrwnBkCinci-u_epipd-G5N%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC096315 Rev A |
| Software Validation – CR | [Completion Report for Software Validation for E19582 Curing Oven Máximo ID ES3222](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgtpxFjCinci-u_epipd-HdH%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC096408 Rev A |
| Software Validation – CR | [Completion Report for Software Validation for E19575 Automated Sand Blaster ID ES3215](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgsurEhCinci-u_epipd-Ha0%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC096602 Rev A |
| Software Validation - CR | CR for Software Validation for E20094 Drying Room HVAC Max ID: ES4035 | PRC096323 Rev A |
| Draft Procedures | [Manufacturing Process Control Plan for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwu3FeCinci-u_epipd-xUy%7Ex3PrsDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PR001712 Draft |
| Draft Procedures | I-Sheet | SPE004694 Draft |
| Draft Procedures | Process Specification for MIMAS Coating | PR001753 Draft |
| Draft Procedures | pFMEA | RMD001679 Draft |
| Draft Procedures | [Material Specification for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwvlgjCinci-u_epipd-xUJ%7Ex3SpcDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | SPE004695 Draft |
| Draft Procedures | [Hoja de set-up MIMAS Coating](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgktTThCinci-u_epipd-GGW%7Ex2SteFrm%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | FRM004270 Draft |
| Draft Procedures | Coating Area L-173 | TR011320 Draft |
| Draft Procedures | Cooking Oven for Paint | TRP001924 Draft |
| Draft Procedures | Cleaning Electrodes in Oven | TRP001923 Draft |
| Draft Procedures | Electrode Loading In Paint Area | TRP001922 Draft |
| Draft Procedures | Electrode Unloading and Inspection in Paint Area | TRP001921 Draft |
| Draft Procedures | Painting | TRP001920 Draft |
| Draft Procedures | Sandblasting | TRP001919 Draft |
| Draft Procedures | Ultrasonic Washer | TRP001918 Draft |
| Draft Procedures | Electrode Sorting | TRP001917 Draft |
| Operation Qualification CR | Completion Report for OQ for Mimas Coating Equipment L173 | PRC096955 Rev A |
| Engineering Study | Coating Area Engineering Study | PRC097400 Rev A |

1. Insulation

The Insulation portion of this Performance Qualification can be executed once all the pre-requisites listed for Insulation process have been approved and released.

Table 5 - Pre-Requisites for Insulation

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification Completion Report | Completion report of Installation Qualification for Pad Printers with Vision System Line 175 | PRC095098 Rev A |
| Installation Qualification Completion Report | Installation Qualification Protocol for Heat Shrink Oven E19587 Completion Report | PRC095232 Rev A |
| Installation Qualification Completion Report | Installation Qualification Protocol for Tubing Cutters E19585 & E19586 Completion Report | PRC095224 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 Completion Report | Completion Report for E19590 Pad Printers with Vision System Software Validation Maximo ID ES3230 and ES3257 | PRC095255 Rev A |
| Software Validation Completion Report | Completion report for E19587 Heat shrink oven software validation Maximo ID ES3227 | PRC095423 Rev A |
| Software Validation Completion Report | Completion report for software validation for Tubing Cutter 1 E19585 Maximo ID ES3225 | PRC095632 Rev A |
| Software Validation Completion Report | Completion report for software validation for Tubing Cutter 2 E19586 Maximo ID ES3226 | PRC095792 Rev A |
| Operation Qualification CR | Completion Report of Operational Qualification for Pad Printers with vision System Line 175 | PRC096186 Rev B |
| Engineering Study | Heat Shrink Tubing Cutters Confirmation Run Line 175 | PRC097517 Rev A |
| Engineering Study | Pad Printers Confirmation Run 175 | PRC097518 Rev A |
| Engineering Study | Modified Blades Confirmation Run Line 175 | PRC097704 Rev A |
| Draft Procedures | Process Specification | PR001720 Draft |
| Draft Procedures | Control Plan | PR001754 Draft |
| Draft Procedures | I-Sheet | SPE004694 Draft |
| Draft Procedures | [Material Specification for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwvlgjCinci-u_epipd-xUJ%7Ex3SpcDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | SPE004695 Draft |
| Draft Procedures | pFMEA | RMD001679 Draft |
| Draft Procedures | Insulation area L-175 | TR011321 Draft |
| Draft Procedures | Logo Printing | TRP001925 Draft |
| Draft Procedures | Insulation Cutting Machine | TRP001926 Draft |
| Draft Procedures | Insulation Baking | TRP001927 Draft |
| Draft Procedures | Discharge of electrodes in the insulation area | TRP001928 Draft |
| Draft Procedures | Electrode Inspection (Insulation) | TRP001929 Draft |
| Draft Procedures | Inspection, cleaning and colocation of cap | TRP001930 Draft |
| Draft Procedures | Inspection of Electrodes in Insulation (paint defects) | TRP001931 Draft |
| Draft Procedures | Insulation Assy | TRP001932 Draft |
| Draft Procedures | Electrodes Loading into Insulation Jig | TRP001933 Draft |

1. Packaging

The Packaging portion of this Performance Qualification can be executed once all the pre-requisites listed for Packaging process have been approved and released.

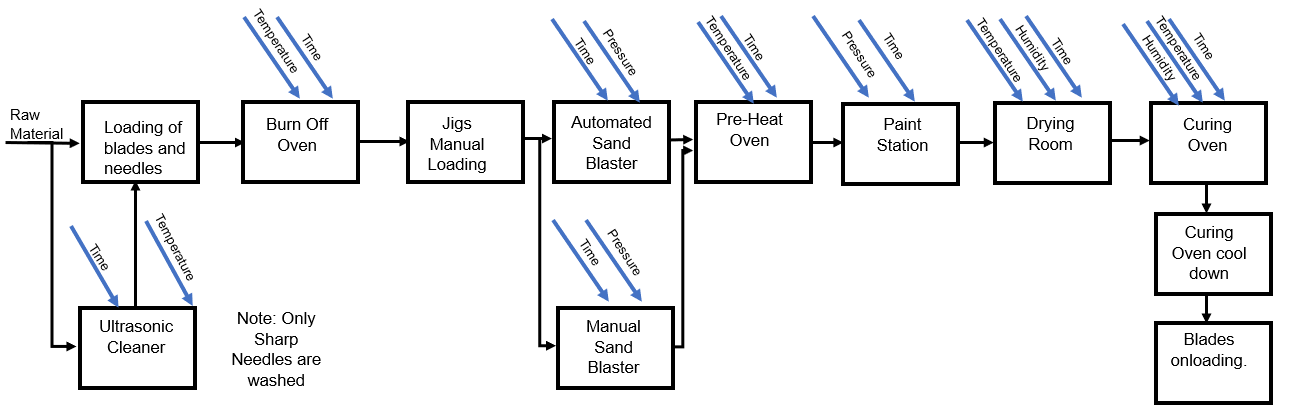
Table 6 - Pre-Requisites for Packaging

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Response Surface DOE | Multivac Sealer With in-line Printer E19592 Screening DOE | PRC095424 Rev A |
| Installation Qualification – CR | Completion Report IQ for Multivac Sealer Machine with in-line printer E19592 | PRC095110 Rev A |
| Software Validation – CR | Completion Report for Software Validation for E19592 Multivac Sealer with In-Line Printer | PRC095603 Rev A |
| Test Method Validation-CR | Visual Inspection | PRC096189 Rev A |
| Test Method Validation-CR | Completion Report for Test Method Validation for Vision System Presence of Device for E19592 Multivac Sealer With in-line Printer | PRC095724 Rev A |
| Test Method Validation-CR | Completion Report for Test Method Validation for Vision System Print Inspection for E19592 Multivac Sealer With in-line Printer | PRC095726 Rev A |
| Test Method Validation-CR | [Test Method Validation Completion Report for Packaging Visual Inspection](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgxvzkaCinci-u_epipd-Hoh%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC096700 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 |
| Installation Qualification CR | [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=')) | PRC095686 Rev A |
| Software Validation CR | Completion Report of Software Validation for Automated Label Applier E20172 | PRC095821 Rev A |
| Operation Qualification CR | Completion Report for Multivac Sealer with-in Line Printer E19592 | PRC095722 Rev A |
| Operation Qualification CR | Completion Report for Operational Qualification for Automated Label Applier E20172 | PRC096305 Rev A |
| Installation Qualification CR | Completion Report for Installation Qualification for E20295 Bulk Packaging Smart System, E20296 Bulk Packaging and E20129 Label Printer | PRC097208 Rev A |
| Software Validation CR | [Completion Report of Software Validation for Bulk Packaging Smart System E20295](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuqIPdCinci-u_epipd-LYE%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC097496 Rev A |
| Test Method Validation-CR | Completion Report for Test Method Validation for Counting Scale and Labeling System E20295 Bulk Packaging Smart Scale | PRC097409 Rev A |
| Test Method Validation-CR | Completion Report for Test Method Validation for Counting Scale System E20296 Bulk Packaging Weight Scale | PRC097411 Rev A |
| Installation Qualification CR | [Completion Report for Installation Qualification for Automated Label Applier E20172](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuwNAgCinci-u_epipd-L0R%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC097511 Rev A |
| Software Validation CR | [Software Validation Completion Report for E20172 Automated Label Applier](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuxdpiCinci-u_epipd-L0I%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC097513 Rev A |
| Operational Qualification CR | Completion Report for Operational Qualification for Automated Label Applier E20172 | PRC097515 Rev A |

# MANUFACTURING PROCESS FLOW

The complete manufacturing process for Megadyne consist of three sections: PTFE Coating (Line 173), Insulation (Line 175) and Packaging (Line 174).

## The Process Specification PR001753 Rev Draft for PTFE Coating (Line 173), provides step-by-step instructions for the process performed using the equipment and fixtures in the coating area and listed in Table 3.



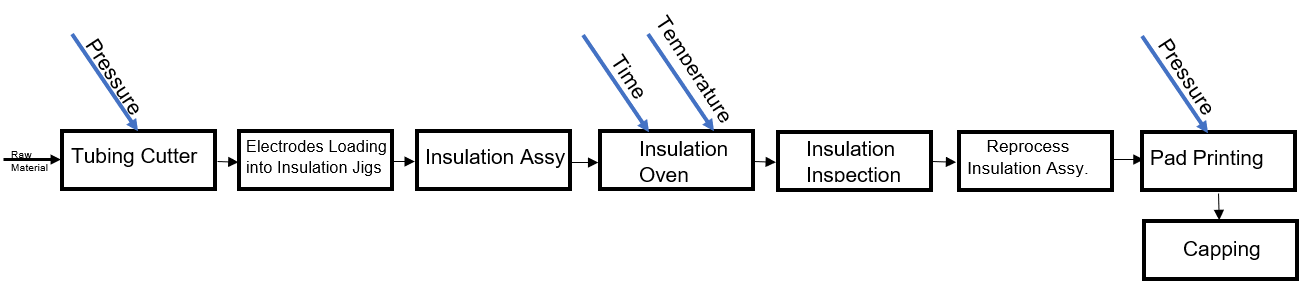
## Coating Process:

* Ultrasonic Washer (Only codes 0118 & 0118A).
  + Electrodes are cleaned with an ultrasonic washer.
* Heat Clean.
  + Heat cleaning process to ensure that bare electrodes are properly cleaned in preparation for a coating application.
* Electrode Sorting.
  + Perform the sorting of electrodes in order to have a correct orientation to load into jigs.
* Loading Coating Jigs.
  + Load electrodes into coating jigs, align and tape in place.
* Sandblasting.
  + Sandblasting & blow-off process used to enhance coating adherence to electrode substrate.
* Preheat.
  + Warms parts prior to coating application to facilitate continuous coverage.
* Coating.
  + Coating application process used to apply PTFE coating to electrodes and ensure consistent coating thickness and good overall coverage.
* Drying.
  + ’Fresh’ coated parts placed in a controlled environment to remove solvent prior to cure.
* Cure Oven.
  + Electrode coating curing process to ensure that the Megadyne Non-Stick Polymer Coating is properly cured and affixed to the electrode substrate.
* Part Cool and Unload Electrodes.
  + Electrodes are cooled and removed from coating jigs in order to pass to the insulation process.
* Inspection.
  + Inspect coated parts under magnification for coating defects to ensure acceptable coating finish.

## Assembly manual training operation for Megadyne Line 173.

* Main assembly training manual.
  + TR011320A Coating Area L-173.
* Manual training operations for Megadyne Line 173.
  + TRP001924A Curing Oven for Paint.
  + TRP001923A Cleaning Electrodes in Oven.
  + TRP001922A Electrode Loading in Paint Area.
  + TRP001921A Electrode Unloading and Inspection in Paint Area.
  + TRP001920A Painting.
  + TRP001919A Sandblasting.
  + TRP001918A Ultrasonic Washer.
  + TRP001917A Electrode Sorting.

## The Process Specification PR001720 Draft for Insulation(Line 175), provides step-by-step instructions for the process performed using the equipment and fixtures in the insulation area and listed in Table 3.



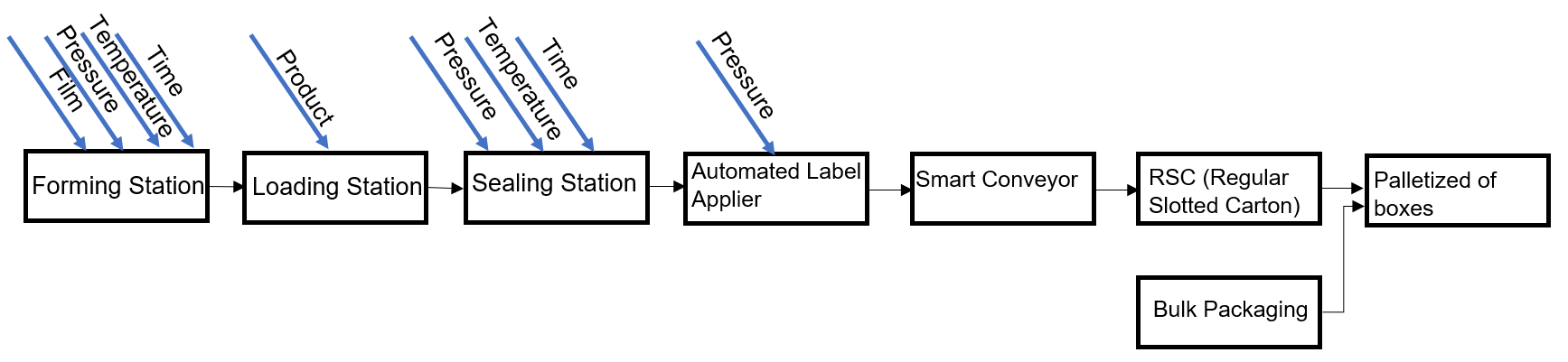
## Insulation Process

* 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.

## The Process Specification PR001736 Draft, provides step-by-step instructions for process performed using the Packaging Machines (Line 174).



## Packaging Process.

* Multivac.
  + This operation consists in the packaging process on the Multivac.
* Labeling.
  + This operation consists in apply labels to sales unit box, bags and shipper boxes.
* Bulk Packaging.
  + This operation consists in packaging electrodes in bulk into bags to be shipped.
* RSC (Regular Slotted Carton)

This process includes the packaging of SU (Sales Units) into shipper boxes and palletizing operations.

## Assembly manual training operation for Megadyne Line 174.

* Main Assembly training manual.
  + TR011319A Packing area L-174.
* Manual training operations for Megadyne Line 174.
  + TRP001934A Bulk Packaging.
  + TRP001935A Sales Unit Packaging.
  + TRP001936A RSC Final Packaging.
  + TRP001937A Loading of Components.
  + TRP001944A Label Applying in Sales Unit Box.

# REQUIREMENTS AND ACCEPTANCE CRITERIA / CTQ LIST

## The Critical to Quality (CTQ) aspects of the products to be made during this Performance Qualification are shown below. Each of the PQ runs must meet the Acceptance Criteria following the Material Specification SPE004695 Draft, MS00003(only packaging) Draft and pFMEA RMD001679 Draft.

## Requirements and acceptance criteria are listed in Table 7 below

Table 7 - CTQ List

| Process/Line | Attribute | Test Method | Specification | Acceptance Criteria |
| --- | --- | --- | --- | --- |
| PTFE Coating/Line 173 | Uniform Paint | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Without Cracks (Excess of paint) | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Without spots (Bad paint preparation) | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Without color variation (water marks) | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Without contamination (debris, inclusion, bumps, spots) | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Incomplete coverage (dark color, Lack of paint) | Visual Inspection | SPE004695 Requirements | According to Table 8 |
| Cosmetic | Visual Inspection | SPE004695 Requirements | No Damage |
| Insulation/Line 175 | Heat Shrink | SPE004695 | Wrong, missing or misassembled / damaged heat shrink tubing / PTFE tubing. Wrong location or incomplete recovery. | According to Table 8 |
| Tubing Length | PRC096184 Rev A | Tubing length must meet required length after it is cut to length and has gone thru heat shrink process | Shrink tube length within accepted tolerance |
| Pad Printing | SPE004695 | The logo (marketed name of device or trademark) on device is incorrect, missing, illegible, or damaged | Logo is present and legible.  According to Table 8 |
| Print Distance from Stem | PRC096184 Rev A | Logo must be printed according to product code specification. | Logo printing distance within accepted tolerance from stem |
| Packaging/Line 174 | MS00003 | Visual Inspection | MS00003 Requirements. | According to Table 8 |
| Cosmetic | Visual Inspection | Unit Box Pre-Printed free of damages | No damage on the Printed box or label |
| Legible | Visual Inspection | Information printed legible and correct | Legible and correct information |
| Integrity | Visual Inspection | Label correctly attached to the Unit Box Pre-Printed/Bag/Unit Box/Shipping Box | Uniform label, firmly and securely attached to the Unit Box Pre-Printed |
| Location | Visual Inspection | Label located as per top assembly drawing | Label location matches specified location in drawing |

# PROCESS PARAMETERS

Parameters used for this protocol will be categorized as nominal. Process parameters are as per Process Specifications PR001753 Draft (Coating PTFE Line 173), PR001720 Draft (Insulation Line 175) and PR001736 Draft (Packaging Line 174), according to the production line.

# Operating Procedures

Raw materials used in this protocol will be inspected for RMI by Megadyne only and will not be inspected by INDEPENDENCIA site.

The Manufacturing Procedures, PR001753 Draft (PTFE Coating), PR001720 Draft (Insulation) and PR001736 Draft (Packaging) provides instructions on the processes performed for the equipment in Megadyne Lines 173, 174, and 175.

The operating procedures are detailed in the following documentation and will be attached as supporting file, all documents are in draft revision:

* Control Plan (PR001754) Insulation/Packaging
* Control Plan (PR001763) Coating
* pFMEA (RMD001679)
* I-Sheet (SPE004694)
* Set up (FRM004256 PTFE Coating, FRM004277 Insulation and FRM004256 Packaging)
* instructions of process for:
  + Coating PTFE (Line 173)
    - TRP001917 Electrode Sorting.
    - TRP001918 Ultrasonic Washer.
    - TRP001719 Sandblasting.
    - TRP001920 Painting.
    - TRP001921 Electrode Unloading and Inspection in Paint Area.
    - TRP001922 Electrode Loading in Paint Area.
    - TRP001923 Cleaning Electrodes in Oven.
    - TRP001924 Curing Oven for Paint.
  + Insulation (Line 175)
    - TRP001925 Logo Printing.
    - TRP001926 Insulation cutting Machine.
    - TRP001927 Insulation Baking.
    - TRP001928 Discharge of electrodes in the insulation area.
    - TRP001929 Electrode inspection (insulation).
    - TRP001930 Inspection, cleaning and colocation of cap.
    - TRP001931 Inspection of Electrodes in Insulation (Paint defects).
    - TRP001932 Insulation Assy.
    - TRP001933 Electrodes Loading into Insulation Jig.
  + Packaging (line 174)
    - TRP001934 Bulk Packaging.
    - TRP001935 Sales Unit Packaging.
    - TRP001936 RSC Final Packaging.
    - TRP001937 Loading of Components.
    - TRP001944 Label Applying in Sales Unit Box.

# Training Requirements

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

## Training will be documented by the protocol originator or designee and will consist of reviewing this Performance Qualification Protocol PRC096295 Rev A and its requirements.

## Training will be documented using form FM-0000809 Rev. 15. 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 PRC096296 Rev A

# TEST STRATEGY

The purpose of this testing is to verify that the process Instrument and Final Packaging Assembly (equipment and production associates) are capable of manufacturing products as designed under normal manufacturing conditions.

Multiple equipment of the same brand and model are expected to be qualified for the same process within this PQ.

## Process parameters for the applicable equipment have been established per Operation Qualification for the equipment listed in Table 3 per PRC095721 Rev A, PRC096304 Rev A, PRC096954 Rev A and PRC096184 Rev B.

## Per PR-0000089 Rev 14, this Performance Qualification will include at least three production runs for each one of the product codes selected, the duration of which shall capture process variation both within and between runs. Furthermore, a Finished Goods Inspection for this Performance Qualification is being performed to satisfy the process performance (reliability) requirements per CP0030 Rev AJ through an acceptance plan in section 13.

## Batches will be produced as not saleable product.

## The product codes in Table 2 above will be used for the execution of this protocol. These product codes will cover the two tip profiles in scope of this qualification and the complete assembly process, including normal and bulk packaging.

## Any instrument failure or non-conformance found in any of the three portions of this protocol, will only affect that section and will leave the others unaffected. However, analysis and corrective actions must be documented under Non-Conformances in EtQ System per 100254122 Rev. 17.

### Only the section where the failure is found will be affected and will only fail that portion of the protocol.

# SAMPLING PLAN AND RATIONALE

## 100% in-process visual inspection will be performed by the line associates of the total quantity that will be produced per Tables 10 - PTFE Coating (Line 173), 11 – Insulation (Line 175), 12 – Normal Packaging and 13 - Bulk Packaging (Line 174).

## This validation is intended to qualify appropriate performance of the equipment listed in Table 3 for product codes described in Table 2.

## A sample size of 299 per product code is required to adequately perform testing for attribute data. The sample size is based on the Binominal Distribution (as defined below) assuming 99% reliability (process performance) at 95% confidence and with an acceptance number c=0 for Class 0 and Class I defects.

 where:

Pc = The probability of getting “c” defects in “n” samples with “p” percent defectives.

## The “Accept/Reject Numbers” listed below are calculated using the Binomial Distribution function shown above and the AQL’s stated in CP0030 Rev AJ, section 4.2.6 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 Rev AJ, section 4.2.6 and the “Accept/Reject” numbers truncated to the lower whole number.

**Table 8 - 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 |

### Only for Bulk Packaging the FGQA Technician will inspect the 6 individual boxes (100% product), for the rest of processes the inspection will be 299 individual pieces.

## Attribute testing for coating defects will be performed by the Quality Technician using the sample size shown in Tables 10(PTFE Coating Line 173), 11(Insulation Line 175), 12(Normal Packaging Line 174) and 13(Bulk Packaging) and documented in data sheet FMWE0311.1 Rev G.

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

## If the criteria for success are not met for any portion of this protocol, root cause analysis and corrective action will be identified and documented under as a Nonconformances in EtQ System per 100254122 Rev 17.

### In case there is a defect/rejection related to the changes addressed under this document, this protocol will fail.

# TEST PLAN

## Obtain all required material according to the BOM’s of the product codes in Table 2.

### The Component Engineer or designee will prepare the material required for each one of the batches.

### Component Engineer or designee will fill out the form FRM001436 Rev A at the beginning of each batch.

### Component Engineer or designee will leave the components at the line.

### Once the batch run is finished, the Component Engineer or designee will complete columns (b), (c), (d) and Balance on form FRM001436 Rev A.

## Manufacturing Engineer or designee ensures the nominal parameters of the equipment used for each production line are set accordingly and recorded as loaded parameters in the setup sheet forms FRM004270 Draft (Line 173 PTFE Coating), FRM004277 Draft (Line 175 Insulation), and FRM004256 Draft (Line 174 Packaging).

## Different batches will be created for each setting parameter according to Table 9 which outlines the Performance Qualification batches.

Table 9- Performance Qualification Batches

| **Code** | **Run** | **Batch** |
| --- | --- | --- |
| 0012 | 1 | CCPM12 |
| 2 | CCPM22 |
| 3 | CCPM32 |
|  | | |
| 0012BN5 | 1 | CCPM1B |
| 2 | CCPM2B |
| 3 | CCPM3B |
|  | | |
| 0013 | 1 | CCPM13 |
| 2 | CCPM23 |
| 3 | CCPM33 |
|  | | |
| 0118A | 1 | CCPM18 |
| 2 | CCPM28 |
| 3 | CCPM38 |
|  | | |
| 0014 | 1 | CCPM14 |
| 2 | CCPM24 |
| 3 | CCPM34 |
|  | | |
| 0012M | 1 | CP112M |
| 2 | CP212M |
| 3 | CP312M |

## PTFE Coating Line 173 (Portion 1)

### Attribute testing for coating defects will be performed by the Quality Technician using sample size shown in Table 10 to comply with the performance testing.

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

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

**Table 10 – Quantity to produce and inspect PTFE Coating**

| Product Code | Parameter Condition | Qty to Produce | Qty to inspect by Production | Qty to inspect by Quality |
| --- | --- | --- | --- | --- |
| 0012 | Nominal | 10,800 Approx. | 100% In-process | 299 Individual Pieces |
| 0012BN5 | Nominal | 3,240 Approx. | 100% In-process | 299 Individual Pieces |
| 0013 | Nominal | 10,800 Approx. | 100% In-process | 299 Individual Pieces |
| 0118A | Nominal | 864 Approx. | 100% In-process | 299 Individual Pieces |
| 0014 | Nominal | 10,800 Approx. | 100% In-process | 299 Individual Pieces |
| 0012M | Nominal | 10,800 Approx. | 100% In-process | 299 Individual Pieces |

Note: Each product code will have 3 runs

## Insulation Line 175 (Portion 2)

### Attribute testing for heat shrink and printing defects will be performed by the Quality Technician using the sample size shown in Table 11 to comply with the PERFORMANCE 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/or SME will review rejected samples to determine classification of defect.

**Table 11 – Quantity to produce and inspect Insulation**

| Product Code | Parameter Condition | Qty to Produce | Qty to inspect by Production | Qty to inspect by Quality |
| --- | --- | --- | --- | --- |
| 0012 | Nominal | 10,800 Approx. | 100% In-process | 299 |
| 0012BN5 | Nominal | 3,240 Approx. | 100% In-process | 299 |
| 0013 | Nominal | 10,800 Approx. | 100% In-process | 299 |
| 0118A | Nominal | 864 Approx. | 100% In-process | 299 |
| 0014 | Nominal | 10,800 Approx. | 100% In-process | 299 |
| 0012M | Nominal | 10,800 Approx. | 100% In-process | 299 |

Note: Each product code will have 3 runs.

## Packaging Line 174 (Portion 3)

### Normal Packaging

#### Run a minimum quantity of sealed packages according with Table 12, for visual seal and forming inspection, cosmetic and legible information on the label to identify any possible defects per MS00003 Draft.

#### Attribute testing only for seal defects will be performed by the Quality Technician using the sample size shown in Table 12 to comply with the sample size requirement. No Tyvek lids will be peeled or destroyed during this attribute test.

**Table 12 - Quantity to produce and inspect Normal Packaging**

| Product Code | Parameter Condition | Qty to Produce | Qty to inspect by Production | Qty to inspect by Quality |
| --- | --- | --- | --- | --- |
| 030012 | Nominal | 10,032 Approx. | 100% In-process | 299 Individual Pieces |
| 030013 | Nominal | 10,032 Approx. | 100% In-process | 299 Individual Pieces |
| 030118A | Nominal | 792 Approx. | 100% In-process | 299 Individual Pieces |
| 030014 | Nominal | 10,032 Approx. | 100% In-process | 299 Individual Pieces |
| 030012M | Nominal | 10,032 Approx. | 100% In-process | 299 Individual Pieces |

Note: Each product code will have 3 runs.

#### The Quality Technician will address the results of the inspections using form FMWE0311.1 Rev G.

#### Quality technician will visually inspect samples per Table 12 for cosmetic defects and record results on inspection data sheet FMWE0311.1 and will not tear down or destroy stamped samples for this inspection.

#### The samples will be taken from the individual boxes (Pre-printed) after production associates complete their initial inspection.

#### Second inspection will be performed at RSC area.

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

### Bulk packaging.

#### Run a minimum quantity of bulk non-sterile packages according to Table 13.

#### Perform attribute testing only for cosmetic damage, integrity of the label placed on the box, information printed on the label defects and label placement on the box will be performed by the Quality Technician using the sample size shown in Table 13 to comply with the sample size requirement. No Unit Boxes will be destroyed during this attribute test.

**Table 13 - Quantity to produce and inspect Normal Packaging**

| Product Code | Parameter Condition | Qty to Produce | Qty to inspect by Production | Qty to inspect by Quality |
| --- | --- | --- | --- | --- |
| 0012BN5 | Nominal | 3000 | 100% In-process | 6 individual boxes |

Note: Each product code will have 3 runs.

#### The Quality Technician will address the results of the inspections using the FMWE0311.1 Rev G.

#### The Quality Technician will perform inspections in the RSC area once the unit boxes are ready for inspection and prior to production associates placing the tape on the individual box.

#### Quality technician will visually inspect samples per Table 13 for cosmetic defects and record results in inspection data sheet FMWE0311.1 and will not tear down or destroy stamped samples for this inspection.

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

#### 

# MATERIAL DISPOSITION

Product manufactured as part of this Performance Qualification is not saleable and will be disposed of as scrap after validation has been completed.

Note: Identify the shipper boxes with label NOT FOR HUMAN USE.

# DEVIATION HANDLING

If deviations occur during the execution of this Performance Qualification, they will be handled in accordance with PR-0000089 Franchise Procedure for Validation (Shared) and documented in the Completion Report PRC096296 Rev A.

# Reference Documents

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

| Document Number | Document Title | Revision |
| --- | --- | --- |
| CP0030 | Statistical Techniques Procedure | AJ |
| 100646188 | Validation Deviation Form | 4 |
| PRC094976 | Mimas Non-Coating Equipment Criticality Assessment | E |
| FB003341 | Validation Master Plan for MIMAS project | A |
| WE0020 | Protocols and Engineering Studies | CH |
| WE0293 | Work Instruction for Packaging Process Validation | AW |
| CP0198 | Manufacturing Process Validation Procedure | BF |
| SPE004694 | [Finished Goods Specification for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwvytbCinci-u_epipd-xU0%7Ex3SpcDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| SPE004695 | Material Specification for Megadyne E-Z Clean Electrosurgical Electrodes | Draft |
| 100254122 | Franchise Work Instruction for EtQ Nonconformance Process (Shared) | 17 |
| RMD001679 | [Project MIMAS pFMEA](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEenpxThCinci-u_epipd-CGa%7Ex3RskMgt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| PR-0000089 | Franchise Procedure for Validation (Shared) | 14 |
| 100650854 | Franchise Procedure for Test Method Validation (Shared) | 3 |
| PR001763 | [Manufacturing Process Control Plan for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwu3FeCinci-u_epipd-xUy%7Ex3PrsDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| FRM004269 | [MIMAS Coating Scrap Sheet](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgkud3fCinci-u_epipd-GG0%7Ex2SteFrm%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| FRM004270 | [Hoja de set-up MIMAS Coating](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgktTThCinci-u_epipd-GGW%7Ex2SteFrm%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| PRC091842 | [Mimas Coating Equipment Criticality Assessment](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEfnrpRgCinci-u_epipd-Eo1%7Ex4EngSty%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | C |
| PRC095456 | [IQ CR for Coating Burn-Off Oven E19584/Coating Burn-Off Oven Extractor E19588](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgBjOQiCinci-u_epipd-HUK%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC095481 | [IQ CR Equipment for Sandblasting Area](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgAwUZeCinci-u_epipd-HUm%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096087 | CR for Coating Area | A |
| PRC095994 | [Completion Report the Ultrasonic Cleaner.](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEfgqNbiCinci-u_epipd-D0E%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096203 | [CR for Drying Room](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEdAn5fjCinci-u_epipd-BNR%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096664 | CR for Curing oven w/Truck E19582, Oven Humidifier E19583, Curing Ovens Extractor E19581, T02737 Blades co | A |
| PRC096338 | [Software Validation Completion Report for Megadyne L173 E19578 Pre-Heat Oven ES3218](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgtvjofCinci-u_epipd-Hfu%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096315 | [Completion Report for E19584 Coating Burn-Off Oven software validation Maximo ID ES3224](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgrwnBkCinci-u_epipd-G5N%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096408 | [Completion Report for Software Validation for E19582 Curing Oven Máximo ID ES3222](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgtpxFjCinci-u_epipd-HdH%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096602 | [Completion Report for Software Validation for E19575 Automated Sand Blaster ID ES3215](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgsurEhCinci-u_epipd-Ha0%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC096323 | CR for Software Validation for E20094 Drying Rom HVAC Max ID: ES4035 | A |
| TR011320 | Coating Area L-173 | Draft |
| TRP001924 | Cooking Oven for Paint | Draft |
| TRP001923 | Cleaning Electrodes in Oven | Draft |
| TRP001922 | Electrode Loading in Paint Area | Draft |
| TRP001921 | Electrode Unloading and Inspection in Paint Area | Draft |
| TRP001920 | Painting | Draft |
| TRP001919 | Sandblasting | Draft |
| TRP001918 | Ultrasonic Washer | Draft |
| TRP001917 | Electrode Sorting | Draft |
| PRC096955 | Completion Report For Operational Qualification of Coating | A |
| PRC097400 | Coating Area Engineering Study | A |
| PRC095098 | Completion report of Installation Qualification for Pad Printers with Vision System Line 175 | A |
| PRC095232 | Installation Qualification Protocol for Heat Shrink Oven E19587 Completion Report | A |
| PRC095224 | Installation Qualification Protocol for Tubing Cutters E19585 & E19586 Completion Report | A |
| PRC096204 | Completion Report for Test Method Validation of Pad Printers with vision system E19590 | A |
| PRC095255 | Completion Report for E19590 Pad Printers with Vision System Software Validation Maximo ID ES3230 and ES3257 | A |
| PRC095423 | Completion report for E19587 Heat shrink oven software validation Maximo ID ES3227 | A |
| PRC095632 | Completion report for software validation for Tubing Cutter 1 E19585 Maximo ID ES3225 | A |
| PRC095792 | Completion report for software validation for Tubing Cutter 2 E19586 Maximo ID ES3226 | A |
| PRC096186 | Completion Report of Operational Qualification for Pad Printers with vision System Line 175 | B |
| PRC097517 | Heat Shrink Tubing Cutters Confirmation Run Line 175 | A |
| PRC097518 | Pad Printers Confirmation Run 175 | A |
| 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 |
| ENG-PRT-106 | Test Protocol, Insulation Bond Strength (Megadyne) | A |
| PRC097208 | Completion Report for Installation Qualification for E20295 Bulk Packaging Smart System, E20296 Bulk Packaging and E20129 Label Printer | A |
| PRC095686 | Completion Report for Installation Qualification of Automated Label Applier E20172 | A |
| PRC095821 | Completion Report for Software Validation for E20172 Automated Label Applier | A |
| PR001736 | Process Specification for Megadyne Packaging line 174 | Draft |
| FRM004256 | Set-up Form for Line 174 | Draft |
| PR001754 | Manufacturing Process Control Plan Megadyne | Draft |
| TRP001934 | Bulk Packaging | Draft |
| TRP001935 | Sales Unit Packaging | Draft |
| TRP001936 | RSC Final Packaging | Draft |
| TRP001937 | Loading of Components | Draft |
| TR011319 | [Packing area L-174](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEfilOsjCinci-u_epipd-Eb0%7Ex3AsmTrn%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| PRC096305 | Completion Report for Operational Qualification for Automated Label Applier | A |
| PRC095424 | Multivac Sealer Equipment E19592 Forming and Sealing DOE | A |
| PRC095724 | Completion Report for Test Method Validation for Vision System Presence of Device for E19592 Multivac Sealer With in-line Printer | A |
| PRC095726 | Completion Report for Test Method Validation for Vision System Print Inspection for E19592 Multivac Sealer With in-line Printer | A |
| PRC096700 | [Test Method Validation Completion Report for Packaging Visual Inspection](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEgxvzkaCinci-u_epipd-Hoh%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| TM5016 | Test Method for Determining Package | G |
| PS4026 | Quality Inspections in Packaging | CU |
| PRC095110 | Completion Report for Multivac Sealer Machine with In-Line Printer | A |
| PRC095603 | Completion Report for Software Validation for E19592 Multivac Sealer with In-Line Printer | A |
| PR001447 | Test Method for Determining Minimum Seal Margin Using a Steel Scale | B |
| PRC095722 | Completion Report for Multivac Sealer with-in line | A |
| PRC097496 | [Completion Report of Software Validation for Bulk Packaging Smart System E20295](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuqIPdCinci-u_epipd-LYE%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC097409 | Completion Report for Test Method Validation for Counting Scale and Labeling System E20295 Bulk Packaging Smart Scale | A |
| PRC097411 | Completion Report for Test Method Validation for Counting Scale System E20296 Bulk Packaging Weight Scale | A |
| PRC097511 | [Completion Report for Installation Qualification for Automated Label Applier E20172](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuwNAgCinci-u_epipd-L0R%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC097513 | [Software Validation Completion Report for E20172 Automated Label Applier](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEiuxdpiCinci-u_epipd-L0I%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | A |
| PRC097515 | Completion Report for Operational Qualification for Automated Label Applier E20172 | A |

# ATTACHMENTS

The following are appendices to this document.

| Appendix Number | Attachment Name |
| --- | --- |
| 1 | Supporting File 1 - Protocol Spanish version per WE0020 |
| 2 | Supporting File 2 – Process Specification PR001753 Draft |
| 3 | Supporting File 3 – Control Plan PR001763 Draft |
| 4 | Supporting File 4 – Set up Form FRM004270 Draft |
| 5 | Supporting File 5 – Label Applying in Sales Unit Box TRP001944 Draft |
| 6 | Supporting File 6 – Ultrasonic Cleaner TRP001918 draft |
| 7 | Supporting File 7 – Oven Electrode cleaning TRP001923 Draft |
| 8 | Supporting File 8 – Electrode sorting TRP001917 Draft |
| 9 | Supporting File 9 – Painting area electrode loading TRP001922 Draft |
| 10 | Supporting File 10 – Sandblasting TRP001919 Draft |
| 11 | Supporting File 11 – Painting TRP001920 Draft |
| 12 | Supporting File 12 – Paint coating oven TRP001924 Draft |
| 13 | Supporting File 13 – Electrode unloading and painting area inspection TRP001921 Draft |
| 14 | Supporting File 14 – PFMEA RMD001679 Draft |
| 15 | Supporting File 15- TRP001928A Discharge of electrodes in the insulation area |
| 16 | Supporting File 16- TRP001931A Inspection of Electrodes in Insulation (paint defects) |
| 17 | Supporting File 17- TRP001926A Insulation cutting Machine |
| 18 | Supporting File 18- TRP001933A Electrodes Loading into Insulation Jig |
| 19 | Supporting File 19- TRP001932A Insulation Assy |
| 20 | Supporting File 20- TRP001927A Insulation Baking |
| 21 | Supporting File 21- TRP001929A Electrode inspection (Insulation) |
| 22 | Supporting File 22- TRP001925A Logo Printing |
| 23 | Supporting File 23- TRP001930A Inspection, cleaning and colocation of Cap |
| 24 | Supporting File 24- TR011321A Insulation area L-175 |
| 25 | Supporting File 25- Process Specification PR001720 Draft |
| 26 | Supporting File 26- Process Specification PR001720 Draft Spanish Version |
| 27 | Supporting File 27- Set up Form FRM004277 Draft |
| 28 | Supporting File 28- Material Specification SPE004695 Draft |
| 29 | Supporting File 29- Material Specification SPE004695 Draft Spanish Version |
| 30 | Supporting File 30- I-sheet SPE004694 Draft |
| 31 | Supporting File 31- I-sheet SPE004694 Draft Spanish Version |
| 32 | Supporting File 32- Control Plan PR001754 Draft |
| 33 | Supporting File 33- Control Plan PR001754 Draft Spanish Version |
| 34 | Supporting File 34 – Process Specification PR001736 Draft |
| 35 | Supporting File 35 – Process Specification PR001736 Draft Spanish |
| 36 | Supporting File 36 – Set up Form FRM004256 Draft |
| 37 | Supporting File 37 – Bulk Packaging TRP001934 Draft |
| 38 | Supporting File 38 – Sales unit packaging TRP001935 Draft |
| 39 | Supporting File 39 – RSC Final Packaging TRP001936 Draft |
| 40 | Supporting File 40 – Loading of components TRP001937 Draft |
| 41 | Supporting File 41- Manual Production |
| 42 | Supporting File 42- MS00003 Rev BW Draft |
| 43 | Supporting File 43- FGQA Results |
| 44 | Supporting File 44- DHR Lavadora Ultrasonica |
| 45 | Supporting File 45- DHR Arenado |
| 46 | Supporting File 46- DHR Cargado de Electrodos Pintura |
| 47 | Supporting File 47- DHR Pintura |
| 48 | Supporting File 48- DHR Inspeccion de Pintura |
| 49 | Supporting File 49- DHR Cargado Electrodos Insulacion |
| 50 | Supporting File 50- DHR Colocacion de Insulacion |
| 51 | Supporting File 51- DHR Cortadora de Insulacion |
| 52 | Supporting File 52- DHR Inspeccion de Insulacion |
| 53 | Supporting File 53- DHR Pad Printing |
| 54 | Supporting File 54- DHR Inspeccion, Limpieza y colocacion de Cap |
| 55 | Supporting File 55- DHR Multivac |
| 56 | Supporting File 56- DHR Inspeccion Multivac |
| 57 | Supporting File 57- DHR Empaque a Granel |
| 58 | Supporting File 58- Horno de Coccion en Pintura |
| 59 | Supporting File 59- Sorteo de Electrodos |
| 60 | Supporting File 60 – Aplicacion de Etiquetas |
| 61 | Supporting File 61- Empaque Cajas |
| 62 | Supporting File 62- Empaque Final RSC |
| 63 | Supporting File 63- Descarga Electrodos en Pintura |
| 64 | Supporting File 64- Horno de Coccion en Insulacion |
| 65 | Supporting File 65- Descarga Electrodos en Insulacion |