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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ENGINEERING**  **STUDY** | | | | | | **Document Title** | | | | | | | | | | | **MVP, DP, ECP or**  **SPCR Number** | | | |
| **Heat Shrink Tubing Cutters Confirmation Run Line 175** | | | | | | | | | | | **DC003495** | | | |
| **Originator** | | | | | | **Date**  **Originated** | | | **Account**  **Code** | | **Reference**  **Documents**  (Link in EPICENTER) | | | | | **Batch/Lot**  **Number(s)** | **Product Code/Part Numbers**  (Link in EPICENTER) | | | |
| **Ivan Armenta** | | | | | | 08/21/2020 | | | N/A | | PRC096184 | | | | | N/A | Table 1 | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **Engineering Study Document Type and Approval Governance** | | | | | | | | | | | | | | | | | | | | |
| **Type:** | | **Engineering Studies- Other** | | | | | | | | | | | | | | | | | | |
| **Organization Responsible-**  **Governance** | |  | **New Product Development**  **Pre-Launch/Stabilization**  **(CP0258 or CP0150 if applicable)** | | | |  | **Lifecycle Engineering**  **Post Stabilization (CP0150 if applicable)** | | | | |  | **External**  **Manufacturing**  **(CP0231/CP0150)** | | | |  | **Other** | |
|  | | | | | | | | | | | | | | | | | | | | |
| **Are Pre-Execution Approvals Required?**  **(Review WE0020 Appendix I)** | | | | | | | | | | | | **YES**  **NO** | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **Approval Section**  **(Indicate Approval Status of THIS REVISION)** | | | | | | | | | | | | **Pre-Execution Approval**  **Completion Approval** | | | | | | | | |
| **Function** | | | | **Name** | | | | | | **User I.D.** | | | | | **Signature/Date** | | | | | |
| Originator | | | | Ivan Armenta | | | | | | Iarment2 | | | | | eSig in EPIcenter | | | | | |
| Plant Quality Engineer | | | | Victor Cantu | | | | | | vcantusi | | | | | eSig in EPIcenter | | | | | |
| Lifecycle Quality Engineer | | | | Ihsan Samara | | | | | | isamara | | | | | eSig in EPIcenter | | | | | |
| Lifecycle Design Engineer | | | | Brian Walter | | | | | | Jdiaz24 | | | | | eSig in EPIcenter | | | | | |
| LCE or PM Development Engineer | | | | Moises Hernandez | | | | | | Mhern281 | | | | | eSig in EPIcenter | | | | | |
| Approver | | | | Javier Diaz | | | | | | Jdiaz24 | | | | | eSig in EPIcenter | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **Additional Completion Approvals (N/A If Not Applicable)** (Leave These Spaces Blank at Pre-Approval Phase) | | | | | | | | | |  | | | | | | | | | | |
| **Function** | | | | **Name** | | | | | | **User I.D.** | | | | | **Signature/Date** | | | | | |
| **Test Conducted By** | | | | N/A | | | | | | N/A | | | | | N/A | | | | | |
| **Data Authentication** | | | | N/A | | | | | | N/A | | | | | N/A | | | | | |
| **Product Destroyed By** | | | | N/A | | | | | | N/A | | | | | N/A | | | | | |
|  | | | | |  | | | | | | |  | | | | | | | | |
| **Revision** | **Change Description** | | | | | | | | | | | | | | | | | | |
| A | Original | | | | | | | | | | | | | | | | | | |

**PURPOSE**

The purpose of this Engineering Study is to document the Confirmation Run performed for the equipment listed in Table 1 located at Independencia Plant.

Table 1 - Equipment Information

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Equipment Description | Machine Number | Maximo ID Number | Source Code | Serial # | Supplier |
| 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 |

The purpose is to document objective evidence for the closure of the NR-0148244 generated in Operational Qualification PRC096184 Rev A for the tubing defect found in code 0013 in its lower parameter, and that the process control limits and corrective actions for the Heat Shrink process result in product that meets all predetermined specifications per SPE004695 Rev Draft.

**SCOPE**

The scope of this Engineering Study is limited to 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 listed in Table 1 was used to cut and shrink the tubing on product code in Table 2. This Engineering Study will help to close the NR generated during the execution of the Operational Qualification PRC096184 Rev A for the defect found in code 0013 in its lower parameter.

Table 2 – Engineering Study Materials

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

Running code 0012 for this Engineering Study will serve as a representative sample for code 0013, since these codes share the same process and components for the Heat Shrink process. Operational Qualification PRC096184 Rev B will run one batch per parameter for code 0012 to cover the failure generated in Revision A.

Testing Location:

\*\*Cincinnati Campus (all buildings): Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242

Albuquerque: Ethicon Endo-Surgery, 3801 University Blvd, S.E., Albuquerque, NM, 87106

Torres: Ethicon Endo-Surgery, S.A. de C.V., Avenida De Las Torres No 7125, Colonia Salvarcar 118, Ciudad Juarez, Chihuahua, 32580, Mexico

Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juarez, Chihuahua, 32575, Mexico

Other (please specify):

**CRITERIA FOR SUCCESS**

Requirements and acceptance criteria are listed in Table 3 below.

Table 3 – 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 for Heat Shrink.  Accept 12 / Reject 13 for Class III defect with Heat Shrink. |

100% in-process visual inspection for tubing cutter defects (ex.: folded, wrong length, damaged tubing), heat shrink (ex.: damaged, misplaced, incomplete recovery or wrong tubing) will be performed by the line associates on the total quantity that will be produced.

This Engineering Study is intended to confirm appropriate Heat Shrink process performance using the equipment listed in Table 1 for product codes listed in Table 2.

**STRATEGIES AND ASSUMPTIONS**

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

Training will be conducted by the protocol originator or designee and will consist of performing a review of this Engineering Study (PRC097517) and its requirements.

Batches built under Engineering Study 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.).

**PROCEDURE (Use Attachments if Necessary) Training Applicable (Check One)**  **Yes  No**

1. Training- All personnel associated with the execution of this study must be trained. Associates may be exempt from training if they reviewed/approved this protocol in Epicenter.
2. Machine settings- The input settings shall be adjusted according to Table 4.

Table 4 - Setting Parameters

| Equipment | Parameter | Parameter |
| --- | --- | --- |
| Heat Shrink Oven | Temperature | 345 °F |
| Tubing Cutter 1 | Air supply | 85.0 PSI |
| Tubing Cutter 2 | Air supply | 85.0 PSI |

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.

Table 5 - Sampling size

| **Group** | **Parameter** | **Product Code** | **Build Qty Samples** | **Inspect Qty Samples** |
| --- | --- | --- | --- | --- |
| 1 | Nominal | 0012 | 10000 | 299 |

**EQUIPMENT AND MATERIAL**

Equipment used for this Engineering Study is listed in Table 1.

Material used for this Engineering Study is listed in Table 2.

**PRODUCT DISPOSITION  Destroy (Sign Approval Section)  Other (Detail Below)**

Upon Completion of the engineering study, the marked samples that were produced will be scrapped.

**RESULTS / RECOMMENDATIONS**

The test outlined above was performed per released test methods found in PRC096184 Rev A. The results obtained showed that the acceptance criteria were met for the sampling size stated in Table 5. 10,000 samples were built, and after 100% visual inspection performed by associates, 87 samples were scrapped for minor damages on the tubing.

Samples were run at nominal process setting and inspected for Material Specification Requirements (SPE004695 Rev Draft). Visual inspection, as shown in Table 6, successfully met the requirements per PRC097517 Rev A for code 0012.

Quality technician visually inspected 300 samples from 9,913 per SPE004695 Rev Draft and record results on inspection data sheet FMWE0311.1. See Attachment A for further details.

Table 6 – Heat Shrink Visual Inspection

| Code | Built Samples | Qty inspected | Nominal Parameter | Result |
| --- | --- | --- | --- | --- |
| 0012 | 9,913 | 300 | Pass | Pass |

**CONCLUSION / COMPLETION ACTIVITIES**

As a result of this testing activity, it is concluded that all samples successfully met with acceptance criteria specified in the Engineering Study for the equipment listed in Table 1 and located in Line 175.

The Engineering Study has established by objective evidence that the process parameter settings are capable to make products that meet product requirements.

Product and material used during this Engineering Study will be disposed after validation has been completed.

**ATTACHMENTS**

Attachment A – Heat Shrink Visual Inspection Form

Attachment B - Training Record Form FM-0000809

Attachment C – Set Up Form