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| **ENGINEERING**  **STUDY** | | | | | | **Document Title** | | | | | | | | | | | **MVP, DP, ECP or**  **SPCR Number** | | | |
| **Coating Area Engineering Study** | | | | | | | | | | | **DC003495** | | | |
| **Originator** | | | | | | **Date**  **Originated** | | | **Account**  **Code** | | **Reference**  **Documents**  (Link in EPICENTER) | | | | | **Batch/Lot**  **Number(s)** | **Product Code/Part Numbers**  (Link in EPICENTER) | | | |
| **Omar Ivan Tovar** | | | | | | Sep 14, 2020 | | | n/a | | n/a | | | | | n/a | 0012 | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **Engineering Study Document Type and Approval Governance** | | | | | | | | | | | | | | | | | | | | |
| **Type:** | | **Engineering Study – 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** | | | | | |
| Lifecycle Design Engineer | | | | Brian Walter | | | | | | BWalte16 | | | | | eSig in EPIcenter | | | | | |
| Lifecycle Quality Engineer | | | | Ihsan Samara | | | | | | ISamara | | | | | eSig in EPIcenter | | | | | |
| LCE or PM Development Engineer | | | | Moises Hernandez | | | | | | MHern281 | | | | | eSig in EPIcenter | | | | | |
| Approver | | | | Victor Cantu | | | | | | VCantusi | | | | | 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** | | | | Omar Tovar | | | | | | OTovar | | | | | eSig in EPIcenter | | | | | |
| **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 test results for:

* E20094 Drying Room temperature and relative humidity uniformity, and evidence of monitoring system to display and record real-time temperature and relative humidity conditions inside the Drying Room with capability of operator notification for out-of-range conditions.
* High, nominal, low batches for 0012 blade electrodes to include 30 min., 90 min. and 150 min. drying times to ensure all drying times are represented.
* Qualify oven chambers (E19584 Coating Burn off oven, E19578 Pre heat, and E19582 Curing oven) for high, nominal, and low 0012 batches.

**SCOPE**

Engineering study applies to Mimas coating equipment listed in Table 4.

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**

Successful completion of the following tests:

1. Evidence of monitoring system to display and record real-time temperature and humidity.
2. Run product code 0012 to determine:
   1. High, nominal, low runs in E19584 Coating Burn off oven, E19578 Pre heat, and E19582 Curing oven.
   2. To include 30 min., 90 min. and 150 min. drying times to ensure all drying times are represented.
   3. Each 0012 batch (high, nominal, and low) will have a sample size of 300 blades to adequately perform testing for attribute data.
3. E20094 Drying room temperature and humidity uniformity.

**STRATEGIES AND ASSUMPTIONS**

This engineering study will document the evaluation of the uniformity of temperature and humidity inside E20094 Drying Room. The use of an instrument to display and record real time temperature and humidity during the drying process, as well the build of three batches of 0012 under nominal, low, and high process parameters in equipment where applicable, and those parameters are as per Process Specification in PR001753 Draft. Reference Table 1 for applicable equipment operational settings.

| Equipment | Parameter | ENS12L Low Parameters | ENS12N Nominal Parameter | ENS12H High Parameter |
| --- | --- | --- | --- | --- |
| Burn Off Oven | Temperature | 643°F | 655°F | 667°F |
| Time | 3.8 hrs (2.3 hr cycle / 1.5 hr cool down) | | |
| Pre-Heat Oven | Temperature | 100°F | 110°F | 120°F |
| Time | 30 min | | 150 min |
| Paint Station | Pressure | 16psi | 21psi | 26psi |
| Drying Room | Temperature | SP 75°F (70-80°F actual) | | |
| Time | 30 min | 90 min | 150 min |
| Humidity | SP 50 %RH (40-60 %RH actual) | | |
| Curing Oven | Temperature | 743 °F | 755 °F | 767 °F |
| Time | 3.1 hrs (1.6 hr cure / 1.5 hr cool down) | | |
| Humidifier Output | SP 30% (26-30% actual) | | |

*Table 1 – Operational Settings*

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

All personal associated with the execution of this engineering study must be trained prior to the execution of activities. Associates are exempt from training if they review/approve this engineering study in Epicenter.

1. The input machine settings shall be adjusted according to Table 1 and recorded in the setup sheet FRM004270 draft accordingly.
2. Quantity of blades to produce during this engineering study:

| Product Code | Parameter | Batch | Qty to Produce | Qty to inspect (200% in process) | Qty to Inspect by Quality |
| --- | --- | --- | --- | --- | --- |
| 0012 | Low | ENS12L | 10,800 | 10,800 | 300 |
| Nominal | ENS12N | 10,800 | 10,800 | 300 |
| High | ENS12H | 10,800 | 10,800 | 300 |

*Table 2*

1. All 3 batches will be used as a visual training for associates performing 200% in-process inspection of coated blades. Training will be conducted by the Quality Technician.
2. Quality Technician will visually inspect samples per SPE004695 draft and record results in inspection data sheet FMWE0311.1.
3. A sample size of 300 blades 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, section 4.2.6 for class II and III defects. The calculation for acceptance number “c” assumes 100% inspection, a sample size of n=300 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 4.2.6 and the “Accept/Reject” numbers truncated to the lower whole number.

| 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 |

*Table 3 - Acceptance Criteria*

## Attribute testing for coating defects will be performed by the Quality Technician using the sample size shown in Table 3 and documented in data sheet FMWE0311.1.

## In the event the criteria for success are not met for this study, or any portion of this study, root cause and corrective action will be identified, However, analysis and corrective action must be documented under a Nonconformances in EtQ System per 100254122 Rev. 17

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

### Defects not related to the execution of this protocol will be recorded as observational data but will not affect the outcome of the test.

1. Use Instrument Temperature Humidity Reader, Calibration ID: EE4379, to measure temperature and relative humidity inside drying room during all runs of these engineering study. Data from instrument, of all three batches, to be documented under Attachment C.
2. External supplier temperature and relative humidity readings will be documented under this engineering study to assure uniformity is achieved inside the drying room and during the coated blade drying cycle. Refer to Attachment D.

**EQUIPMENT AND MATERIAL**

Equipment see Table 4.

Material see Table 5.

|  |  |  |
| --- | --- | --- |
| **Equipment Description** | **Equipment Number** | **Maximo Number** |
| Paint Refrigerator | E19576 | ES3216 |
| Paint Roller drum mixer | E19577 | ES3217 |
| Pre Heat oven | E19578 | ES3218 |
| Manual Paint Spray Gun | E19580 | ES3220 |
| Curing Oven w/Truck | `E19582 | ES3222 |
| Oven Humidifier | E19583 | ES3223 |
| Coating Burn-Off Oven | E19584 | ES3224 |
| Blades coating process fixtures | T02737 | n/a |
| Rotary stand fixture | T02738 | ES2909 |
| Paint Booth w/NESHAP Filtration | E19579 | ES3219 |
| Drying Room Humidifier | E20130 | ES3393 |
| Drying Room Humidifier | ES4001 |
| Drying Room HVAC | E20094 | ES4035 |
| Blades loading box fixture 2.75" | T02776 | n/a |
| Curing Rack | T02791 | n/a |
| Water Filtration System | E20189 | ES4327 |
| Coating Modifier Scale | E20258 | n/a |

*Table* 4 *- Equipment*

| **Product** | **Part Number** | **Material Description** |
| --- | --- | --- |
| 0012 | 6010011-01 | Subassembly, F/Blade, I/C (0012) |
| 0012 | 3500086-01 | Substrate, F/B 2.5 Tumbled (0012, 12M) |
| 0012 | 5500001-01 | PTFE Coating |
| 0012 | 5500004-01 | Modifier, PTFE |

*Table* 5 *- Material*

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

Upon completion of the Engineering Study, material used will be disposed.

**RESULTS / RECOMMENDATIONS**

Required:

1. Identify and document evidence of monitoring system to display and record real-time temperature and humidity inside drying room during the drying process of the 3 batches manufactured for this engineering study.
2. Run product code 0012 to determine:
   1. High, nominal, low runs in E19584 Coating Burn off oven, E19578 Pre heat, and E19582 Curing oven.
   2. To include 30 min., 90 min. and 150 min. drying times to ensure all drying times are represented.
   3. Each 0012 batch (high, nominal, and low) will have a sample size of 300 blades to adequately perform testing for attribute data.
3. Provide evidence of E20094 Drying room temperature and humidity uniformity during a complete PTFE coating drying process.

Result:

1. Temperature Humidity Reader, Calibration ID: EE4379 was used to monitor real time temperature and humidity inside E20094 Drying room during all manufactured 3 batches. Temperature and relative humidity documented were inside defined working ranges (Temperature 70°F–80°F, Relative Humidity 40%-60%) during the PTFE drying process for the 3 batches (Refer to Attachment C).
2. 3 batches of product code 0012 were manufactured under the settings shown in Table 1 – Operation Settings.
   1. All 3 batches met the required build quantity and all applicable working parameters were documented under each batch setup (Refer to Attachment B).
   2. After FGQA inspection, all 3 batches met the quality requirements defined by this engineering study (Refer Attachment B).
3. External supplier (Dynatec) measured and documented evidence of temperature and relative humidity uniformity inside E20094 Drying room, providing satisfactory results (Refer to Attachment D).

**CONCLUSION / COMPLETION ACTIVITIES**

The engineering study has met the criteria of success and the equipment E19584 Coating Burn off oven, E19578 Pre-heat, and E19582 Curing oven produced satisfactory product under Nominal, Low and High parameters. Equipment E20094 Drying room produced satisfactory product under 30 min., 90 min. and 150 min. drying times.

Based on the results, evaluated equipment are stable and comply with the defined requirements. It was showed that the product inspection results met the acceptance criteria.

**ATTACHMENTS**

Attachment A – Training Record.

Attachment B – Batch documentation.

Attachment C – Temperature/Relative Humidity drying room readings.

Attachment D – Supplier Drying room uniformity evidence.

Attachment E – BOM.