**Phase 3.0 Acceptance and Closeout**

Phase 3 of this ERR should be completed prior to OQ/PQ execution. This revision of the ERR should reflect the equipment and process as delivered to the final assembly location.

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| **P3.1 Component / Sub-Assembly Identification and Status:**   Updated  No Change |
| See [Appendix A](#Appendix_A) for Part Name, Drawing Number and Revision Levels. Any additions or modifications since the initial revision of this ERR shall be documented in Appendix A. |

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| **P3.2 Product Requirements**   Updated  No Change |
| Reference [Appendix B](#Appendix_B) for Product Requirements. Any additions or modifications to the product requirements since the previous revision of this ERR shall be documented in Appendix B. |

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| **P3.3 Process Description**   Updated  No Change |
| Reference [Appendix C](#Appendix_C) for SIPOC. Any additions or modifications to the SIPOC since the previous revision of this ERR shall be documented in section C1.1 of Appendix C. |
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| **3.4 Operational Requirements**  Updated  No Change |
| Any modifications to the operational requirements since the initial revision of this ERR shall be documented in section P1.8 |
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| **P3.5 Assembly / Packaging Line Layout**  Updated  No Change |
| Any modifications to the line layout since the initial revision of this ERR shall be documented in section P1.9 and a new line layout shall be attached. |

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| **P3.6 Gages / Calibration**  Updated  No Change |
| Reference [Appendix D](#Appendix_D) for Gages and Calibration. Identify for each measurement the type of gage utilized, the expected calibration range, and status. Any additions or modifications to the gages or calibration strategy since the previous revision of this ERR shall be documented in Appendix D. |

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| **P3.7 Gage R&R studies**  Updated  No Change |
| Reference [Appendix D](#Appendix_D) for Gage R&R strategy. Identify the strategy for each gage R&R study to be performed. Any additions or modifications to the gage R&R strategy since the previous revision of this ERR shall be documented in Appendix D. |

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| **P3.8 Gage Compatibility**  Updated  No Change |
| Reference [Appendix D](#Appendix_D) for Gage compatibility requirements. Any additions or modifications to the gage compatibility Phase since the previous revision of this ERR shall be documented in Appendix D. |

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| **P3.9 Equipment Capability**  Updated No Change |
| Reference [Appendix D](#Appendix_D) for Equipment Capability requirements. Any additions or modifications to the equipment capability requirements since the previous revision of this ERR shall be documented in Appendix D. |

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| **P3.10 PFMEA**  Updated  No Change |
| If in Phase II of the ERR a PFMEA was unavailable or has since changed, update the information in the following table.   |  |  |  | | --- | --- | --- | | **PFMEA Document #** | **Revision (if draft, indicate draft date)** | **Product code(s) in scope of the PFMEA** | |  |  |  | |

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| **P3.11 Control Plan**  Updated No Change |
| If in Phase II of the ERR a Control Plan was unavailable or has since changed, update the information in the following table.   |  |  |  | | --- | --- | --- | | **Control Plan Document #** | **Revision (if draft, indicate draft date)** | **Product code(s) in scope of the CP** | |  |  |  | |

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| **P3.12 Equipment FMEA**  Updated  No Change  Not required |
| EFMEA if required shall be completed prior to this revision of the ERR. EFMEA shall be loaded to EPIcenter as an attachment to the Phase III revision of this ERR. |

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| **P3.13 Software Design Review**  Completed  Not required |
| Software design review if required per Appendix E shall be completed prior to completing this phase of the ERR. Software Design Review Checklist from FRM003589 shall be loaded to EPIcenter as an attachment to the Phase III revision of the ERR. |

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| **P3.14 Equipment Deliverables Checklist**  Completed |
| Equipment Deliverables Checklist shall be completed prior to this revision of the ERR. Equipment deliverables utilizing FRM003591 shall be loaded to EPIcenter as an attachment to this revision. |

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| P3.15 Software Development & Validation  Complete  NA |
| Review [Appendix E](#Appendix_E) to confirm the information. (For instance, change in equipment software complexity or risk detection profile) |

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| **dglxasset[1]** | **Once Phase III is completed, Upload the following documents to EPIcenter.** | | | | | | | |
| **P3.16 Equipment Development Documentation Table** | | | | | | | |
| **The following documentation is attached to this ERR per identification below.** (Insert “N/A” if not applicable.) | | | | | | | |
| **Attachment ID** | | **Form Number** | | | **Description** | | |
|  | | N/A | | | Assembly Line Layout | | |
|  | | FMWE0222.4 | | | Applicable Lines of Process FMEA (if shared via attachment, otherwise “N/A”) | | |
|  | | FRM003587or similar. | | | Equipment FMEA (if applicable) | | |
|  | | FRM000486 | | | Applicable Lines of Control Plan (if shared via attachment, otherwise “N/A”) | | |
|  | | FRM003588 | | | Equipment Design Review Checklist | | |
|  | | FRM003589 | | | Equipment Software Requirements Review (if applicable)  Equipment Software Design Review Checklist (if applicable) | | |
|  | | FRM003591 | | | Equipment Deliverables Checklist | | |
|  | | FRM002147 | | | Interim Ergonomic and Safety Equipment Evaluation | | |
| Preliminary WRAPS Assessment Report | | |
| ISO13849 Assessment Report (if Applicable) | | |
| Strawman Model (if Applicable) | | |
|  | | N/A | | | Equipment User Manual | | |
|  | | N/A | | | Purchased Component Manual | | |
|  | | N/A | | | Spare Parts List and Quote | | |
|  | | N/A | | | Software Licenses (For all of the shelf software utilized within the equipment | | |
| **The following documentation is loaded into EPIcenter under the identified document numbers.** | | | | | | | |
| **Document Number** | | | **Description** | | | | |
|  | | | Gage Studies - R&R and/or Compatibility (ref. WE0419 and WE0020) | | | | |
|  | | | Software Validation (ref. CP0198, WE0179, WE0020, and FMWE0020.7) | | | | |
|  | | | Capability Study (ref. CP0198 and WE0020) | | | | |
|  | | | Characterization Study (ref. WE0020) | | | | |
|  | | | Factory Acceptance Test (ref. WE0179 and WE0020) | | | | |
|  | | | Electronic Software Copy of all Equipment Files (ref. CP0198 and WE0179) | | | | |
|  |  | | | | | | | |
| **P3.17 Phase III Approval (Indicate approval status of this revision)**  (Reference WE0179 Appendix I P3.17 for Approval Matrix.) | | | | | | | |
| **Prerequisite for IQ Build** | | | | | | | |
| **Function** | | | | **Name** | | **User I.D.** | **Signature/Date** |
| Individual Responsible for the Equipment | | | | Omar Ivan Tovar | | Otovar | eSig in EPIcenter |
| PM Manager | | | | Rafael Palma | | RPalma | eSig in EPIcenter |
| Quality Engineer | | | | Victor Cantu | | VCantusi | eSig in EPIcenter |
| MEST Equipment Engineer | | | | Javier Diaz | | JDiaz24 | eSig in EPIcenter |
| NPI Manufacturing Engineer | | | | Adan Jimenez | | AJimen16 | eSig in EPIcenter |
| Equipment Supplier Project Manager (Non-Ethicon) | | | | n/a | | n/a | n/a |

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**Appendix A Component / Sub Assembly Identification and Status**

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| **A1.1 Component / Sub-Assembly Identification and Status:** | | | | |
| **Part Name** | **Drawing number** | **Drawing Rev. (if applicable)** | **Image of Part** | **Comments** |
|  |  |  |  |  |
|  |  |  |  |  |
| Method of component revision control / notification: | | | | |

**Appendix B Product Requirements**

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| **B1.1 Product Requirements** |
| State product requirements relevant to the equipment design. Reference WE0724 for the procedure that identifies and describes the cascade of product requirement levels.  Note:PLR=Product Level Requirement, SLR=System Level Requirement, SSR=Sub-System Level Requirement, SAR=Sub-Assembly Requirement, APR = Assembly Process Requirement  **READ Then Delete this Text Box.** If product requirements are yet to be defined; plan for update of product requirements during the equipment design review. |

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| **Design Requirements Workbook Document #** | **Revision (if draft, indicate draft date)** | **Product code(s) in scope of the workbook** | **Location of Relevant Requirements** |
|  |  |  | Included with ERR Package.  included in table below  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  N/A – There are no specific product requirements applicable to this station. Refer to part drawings and SIPOC for the relevant information to equipment development. |

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| **READ Then Delete this Text Box** Delete the table below if requirements are communicated via an attachment. | | | | |
| *Requirement 1:* | | | | |
| **Requirement Name** | **Requirement** | **Requirement Number** | **Product Code(s)** | **Defect Class** |
|  |  |  |  |  |

**Appendix C SIPOC**

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| **C1.1 Process Description -** SIPOC Diagram of proposed process (explicit description of the process exclusive to the equipment within this requirement | |
| **SUPPLIERS**  (RESOURCE PROVIDER) | **READ Then Delete this Text Box.** Identify specific suppliers that provide inputs to the process. This includes the facility housing the process, the utility with which the product is provided to the station, and the condition of the input component or assembly. Consider the supply of all equipment, tools, and components.  Example:   1. Device Sub-Assembly x-y from op10 consisting of components x and y 2. Sub-assembly is presented on conveyer with handle facing the op20 operator |
| **INPUT**  (INPUT TO THE PROCESS) | **READ Then Delete this Text Box.** Define the material, service and/or information that are used by the process to produce the outputs. This should include components, component packaging, tools, fixtures, holding stations, bins, handling mechanisms (bowl feed, robot pick/place), utilities, and associates. Consider the bill of materials as needed.  Example:   1. Component z located on a plastic tray (size: 8” x 11”, holds qty 48 z components). This tray has a shelve located near the loading portion of the station 2. Hand Tool 1, to be used with component z for this station   Should include the key component characteristics related with the process. |
| **PROCESS**  (PROCESS STEPS) | **READ Then Delete this Text Box. This is the most critical section of the SIPOC.** Define the sequence of activities needed to add value to the inputs in order to produce the outputs. Describe, **in detail**, how the parts will be loaded, assembled, inspected, and unloaded. Consider any process flow diagram and/or control plan as needed. Highlight equipment functions that create or establish device critical to quality or Delta E features that require specific ergonomic or safety focus, or that are part of assembly line critical control points.  Example:   1. Place sub-assembly x-y into appropriate nest 2. Place component z onto sub-assembly x-y by using hand tool 1 3. Press opto-button, machine recognizes presence of sub-assembly and commences pressing operation 4. Upon cycle completes, as identified by appropriate cycle complete sensor, sub-assembly x-y-z is removed from station |
| **OUTPUT**  (OUTPUT FROM THE PROCESS) | **READ Then Delete this Text Box.** Identify all outputs from the process. This should include information valuable to the customer including test acceptance criteria, data (variable and attribute), and critical control points. Holding fixtures of the output (passing and failing product) should also be considered. Include any device serialization/marking and packaging discard details. Consider any relevant PFMEA and/or control plan steps as needed.  Example:   1. Sub-assembly x-y-z is placed on conveyer that leads to op30 2. Press force data is streamed, via usb cable, to Ethicon provided CPU |
| **CUSTOMER**  (RECEIVE OUTPUT FROM THE PROCESS) | **READ Then Delete this Text Box.** Describe the customers of the process described. All users of the output (passing and failing product) should be considered. Include consideration of inventory handling sufficient to accommodate 3 hours of expected production if feasible.  Example:   1. OP30 operator receives sub-assembly x-y-z from conveyer, handle side first 2. CPU receives press force data and is uploaded to process control software |

**Appendix D Gages**

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| **D1.1 Gages / Calibration** |
| Identify for each measurement the type of gage utilized, the expected calibration range, and status.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Requirement Number** | **Measurement Description** | **Type of Gage** | **Calibration Range** | **Critical / Non-Critical / Exempt** | |  |  |  |  |  |   Refer to CP0190 and FMCP0190.1 for further details on gage classification for Critical / Non-critical / Exempt.  Calibration(s) are to be conducted within the equipment as a system (measurement device & signal conditioner). Equipment design must include provisions for calibration for jigs, weights, transducers etc.  Document any deviations: |
| **D1.2 Gage R&R study/s required?** |
| If the equipment under development is a gage (leak tester, torque tester, etc.) or performs post-operation measurements (inspecting the location of a component or feature after performing a gluing operation, etc.), a GR&R shall be performed prior to shipment of equipment on an appropriate ETHICON form or supplier form validated to meet the intent of WE0419.  YES – Gage R&R study is required.  Is supplier responsible for performing the preliminary GR&R Studies?  YES  NO   |  |  |  |  | | --- | --- | --- | --- | | **Characteristic** | **Type of GR&R** | **Process Limits** | **Acceptance Criteria (min)** | |  |  |  |  |   Type of GR&R:**VPT** *– Variable %P/T ,* **VRR** *– Variable %R&R,* **A** *– Attribute,* **D** *– Destructive*  NO – This equipment is not a gage and does not perform post-operation measurements.  NO – This equipment is a gage but only monitors equipment inputs and settings (no component features/outputs). |
| **D1.3 Gage Compatibility/s required?** |
| Gage Compatibility Studies are required when building a duplicate of an existing piece of equipment or multiples of the same equipment.  Gage compatibility studies shall be performed prior to shipment of equipment on an appropriate ETHICON form or supplier form validated to meet the intent of WE0419.  YES – Gage Compatibility study is required.  Is supplier responsible for performing the preliminary Gage Compatibility Studies?  YES  NO   |  |  | | --- | --- | | **Characteristic** | **Acceptance Criteria (statistical difference or acceptance range)** | |  |  |   NO – This equipment is not a gage and does not perform post-operation measurements.  NO – This equipment is not a duplicate of another piece of equipment or multiple copy of the same equipment; it is unique to  the intended product stream.  NO – Other rationale: |
| **D1.4 Equipment Reliability required?** |
| YES – Equipment reliability study is required.  Is supplier responsible for performing the preliminary Process Reliability Study?  YES  NO  List below the individual characteristic(s) that can be assessed and requirements for acceptance. The target should be based on the level of risk associated with the failure of the requirement and agreed upon with quality engineering; refer to the product quality plan, CP0030, and/or CP0198 for acceptance criteria guidance.   |  |  |  |  | | --- | --- | --- | --- | | **Characteristic** | **Dimension + tolerance** (include units) | **Minimum Requirement** | **# of pieces required for study** | |  |  |  |  |   If reliability assessments do not present satisfactory results, a root cause analysis shall be conducted to determine whether or not the equipment or the components are the key contributors.  NO – The equipment does not produce critical or measurable key output characteristics.  NO – Other rationale: |

**Appendix E Software Development and Validation**

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| **E1.1 Software Development & Review of Validation Deliverables** |
| If no software or electronics containing software are used in this equipment, check here:  Appendix E not required  **Software Validation Type (Type 1 or 2)** – **Reference WE0179 (section 4.6.1) for guidance.**   |  |  |  |  | | --- | --- | --- | --- | |  | | **Risk Detection Profile (see WE0179 section 4.4.3)** | | | High | Low | | **Software Complexity Category (see WE0179 section 4.4.4)** | A | Type 1 | Type 1 | | B | Type 1 | Type 1 | | C | Type 2 | Type 1 | |
| **Software Validation Deliverables** – Use the highest number Software Validation Type to determine the Software Validation Deliverables. Reference WE0179 Appendix I for explanation of the Equipment Software Validation Deliverables. For further clarification, reference WE0179 Appendix VI for a flowchart of software validation activities and deliverables per validation type.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Equipment Software Validation Deliverables** | | **Responsibility** | **Type 1** | **Type 2** | | Equipment Software Requirements Review worksheet capturing equipment software requirements & software design description data: FRM003589 (ESRR).  Software Design Review / Checklist (part of ESRR FRM003589) | | Supplier | NOT Required | Required | | Software Validation Protocol FMWE0020.7 | Software Requirements & Traceability Matrix (FMWE0020.7 Appendix 1, created from FRM003589) | Supplier | Required | Required | | Software Design Description (FMWE0020.7 Appendix 2, created from FRM003589) | Supplier | Required | Required | | Software Verification Test Cases (FMWE0020.7 Appendix 3) | Supplier | Required | Required | | 21 CFR Part 11 Assessment Filter (FMWE0020.7 Appendix 4) | Ethicon | Required | Required | | Software Validation Completion Report FMWE0020.3 | | Ethicon | Required | Required | |