Document Number: CA083535
Revision: A
Group: Component Approval Document
Type: Equipment Requirements Review
State: Released
Latest Released: YES
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Equipment & Tooling Requirement Review (ERR) Form					
Equipment Name	**Drying Room HVAC**			**Supplier**	**n/a (off the shelve equipment)**
Equipment Drawing Number	**E20094**	**Revision**	**A**	**Design Status**	☒ **New** ☐ **Existing**
Equipment Type	☒ **Equipment** ☐ **Tooling** ☐ **Fixturing** ☐ **Gage** ☐ **Other:**			**ERR Phase**	☐ **Phase 1** ☐ **Phase 2 Pre-design review** ☒ **Phase 2 Post design review** ☐ **Phase 3**

Originator	Date Originated
Omar Ivan Tovar	Apr 12, 2020

Revision	Change Description
A	Phase 2 Post design review

Phase 1.0 Planning

Phase 1 of this ERR form shall be completed and released in EPIcenter prior to the issuance of a purchase order for tooling or equipment. Reference WE0179 work instructions for completing this form.

P1.1 Objective of the Equipment or Tooling:

Objective of the equipment is to provide controlled temperature into room enclosure. Equipment will work in conjunction with humidifying system to maintain proper temperature and humidity inside enclosure.

P1.2 Reference Documents

All reference documents are identified in WE0179. These documents should be reviewed during initialization of any equipment design activities. Does the supplier have the latest revision of these reference documents? ☐ YES ☐ NO

If no, provide latest released revision to supplier.

List any additional Reference Documents or External Standards (Along with revision levels) that must be reviewed prior to starting equipment design:

Document Number	Document Name	Revision
tbd	tbd	tbd

P1.3 Product Description

Non-stick electrosurgical tips with polytetrafluoroethylene (PTFE) coating for low power setting use.

P1.4 Component / Sub-Assembly Identification and Status:

Reference Appendix A for Part Name, Drawing Number and Revision Levels.

P1.5 Product Requirements (explicit description of the product exclusive to the equipment within this requirement

Reference Appendix B for Product Requirements. Initial Revision of this ERR form to contain as much information as available. Subsequent revisions of this form shall include all known product requirements.

P1.6 Process Description (explicit description of the process exclusive to the equipment within this requirement

Reference Appendix C for SIPOC. Initial Revision of this ERR form to contain at a minimum the Input and Output sections.

P1.7 Product/Process Assumptions

Provide a list of assumptions associated with the product and/or process that may change throughout the development of the equipment. In addition, specify how changes to these assumptions may impact the equipment development.

NOTE: Only preliminary design work and fabrication necessary to accommodate the contingencies below should be included in the quote as a part of phase 1. **Implementation** of the contingencies below **should not be included** in the quote as a part of phase 1. If implemented, the changes will be funded by a PO update or separate quote/PO.

Assumption	Potential Impact Change on Equipment Development
n/a	n/a

P1.8 Operational Requirements

Values Obtained From Project's Supply Chain Strategy Workbook

Year	Overall Demand	Targeted Equipment Capacity Load	MAKE Site Targeted Supply
Year 1	6,000,000	4,800,000	7,500,000
Year 3	7,000,000	5,600,000	8,750,000
Year 5	8,000,000	6,400,000	10,000,000

	% Uptime / Availability	% Speed / Performance	% Yield	% OEE
Percentage	n/a	n/a	n/a	n/a

Machine Cycle Time Per Part (Machine Start to Machine Stop) *(seconds)*	n/a	Overall Machine Cycle Time Per Part (Operator Manual Work + Machine Cycle Time) *(seconds)*	n/a

P1.9 Assembly / Packaging Line Layout Provided?

The line layout is intended to ensure that equipment/fixture access, cycle start button locations, built-in component part storage, automatic rejection of failures, etc. will be optimized for the intended assembly process.

☒ Yes A simple assembly line layout to be provided in an electronic format as an attachment with approximate machine dimensions visible.

☐ No Provide rationale:

Direction of product flow to and from this station (operator facing station)? ☐ Left to Right ☐ Right to Left ☒ N/A

Process Type? ☐ Continuous Flow (Single Piece Flow) ☐ Batch Process, what is projected batch size?

P1.10 Will existing equipment design/s be utilized? ☐ YES ☒ NO If yes, read detail below

Has a detailed review of existing equipment performance, failure modes, and scrap been conducted? ☐ YES ☐ NO

Provide reference document to supplier: n/a

If the proposed equipment design differs from the existing equipment in any way, cite detail regarding the differences:

Unique Software Layout? ☐ Yes ☐ No

P1.11 Equipment Type & Guarding

Configuration: ☐ Table Top ☒ Free Standing/ dedicated Workstation ☐ Continuous Pallet System

Operator Interaction: ☐ Sitting ☐ Standing & Moving ☐ Both Sitting or Standing & Moving *(reference CP0237)* ☒ N/A

Preference of machine guarding for the operator ☐ Light Curtain ☐ Guard Door ☒ N/A

Approach speed / guard location / machine hazards will determine final solution

P1.12 Is a new Chassis required? ☐ YES ☒ NO Existing chassis will be utilized.

Will a Common Chassis design be used as a starting point for the equipment design?

☐ Yes ☐ No If no, provide approximate size__n/a____ If yes, select appropriate Chassis design and provide current drawing revision.

☐ E14792, Size A (32” Wide) w/ front light curtains ☐ E14793, Size B (42” Wide) w/ front light curtains

☐ E14794, Size C (75” Wide) w/ front light curtains ☐ E15577, Size D (32” Wide) w/ front & side light curtains

☐ E15578, Size E (42” Wide) w/ front & side light curtains ☐ Other_____n/a_____

P1.13 Scrap/Reject Handling

How will reject assemblies be handled?

☐Equipment Stoppage that requires password intervention (reserved for defects that could yield Class 0 classification per product material specification)

☐PLC linked Reject Chute or Bin (identification of device presence in scrap location before equipment will commence)

☐ General Scrap Bin or similar

☒ Other, explain: Environmental equipment, does not produce material process scrap.

P1.14 Electro-Static Discharge (ESD) mitigation?	☐ YES ☒ NO	If yes, read detail below

Describe equipment provisions for mitigating ESD (reference WE0725): n/a

P1.15 Particulate Matter/Foreign Material Mitigation needed? ☐ YES ☒ NO Read detail below

Could the part presentation generate, trap, or attract particulate matter (via part transfer from bulk containers to bins, etc.)?
☐ YES ☒ NO

Will execution of this assembly step generate particulate matter? ☐ YES ☒ NO

Could particulate matter be trapped in device or fluid path? ☐ YES ☒ NO

Provide Mitigation Plan based on above: n/a

P1.16 Safety and Ergonomic Requirements

All new or altered J&J owned equipment shall have a safety review conducted by a representative of the Safety Department. This review should be conducted collectively with the engineer responsible for the equipment and an EHS&S representative.

Equipment design must fully comply with CP0237 Safety and Ergonomic Requirements, including (but not limited to) compliance with NFPA 70 and NFPA 79 requirements.

Worldwide Risk Assessment Process Software (WRAPS)

The Worldwide Risk Assessment Process Software (WRAPS) is the tool we at Johnson and Johnson use for documenting and tracking the risk assessment and risk reduction process. It is based on the Preliminary Hazard Analysis (PHA) methodology and provides a pictorial, easy-to-use method for the decision tree processes for risk estimations found in ISO14121 and EN 954-1. All equipment purchased for use in a Johnson and Johnson facility shall have a WRAPS assessment completed. WRAPS assessment is required prior to equipment acceptance and will be performed by Ethicon representatives.

The supplier of the equipment shall conduct a risk assessment according to the ISO13849 standard to meet the performance level and category architecture requirement of the equipment as agreed upon during design review. Reference CP0237 for the minimum required performance Level and Category architecture.

☐ ISO13849 assessment report is required:

☒ ISO13849 assessment report is not provided; rationale: EHS&S WRAPS will be performed in ERR Phase III if necessary.

P1.17 Are Setup Masters required? ☐ YES ☒ NO If YES, read detail below

Provide description of physical setup adjustments required:

Set-up Master	Value	Limit
n/a	n/a	n/a

Setup Masters are required to be stored / contained at machine. Elsewise, a cabinet for storing all line setup masters must also be included for line.

☐ Setup Masters will be stored in the equipment.
☐ Setup Masters will be stored in an auxiliary cabinet included with this ERR.

P1.18 Are Changeover requirements needed? ☐ YES ☒ NO If YES, read detail below

Provide description of changeover methods required (rapid changeover, automated changeover, tooling or nest ID's, etc):

Changeover Feature	Error proofing / method
n/a	n/a

Changeover tooling to comply with Tooling Guidelines listed in WE0725? ☐ YES ☐ NO If NO, provide rationale:

Changeover tooling shall utilize quick changeover methods wherever possible instead of screws/bolts. Changeover tooling/nests are required to be stored / contained at machine; else a cabinet for storing all line setup masters must also be included for line.

☐ Change over tooling will be stored in the equipment.

☐ Change over tooling will be stored in an auxiliary cabinet included with this ERR.

☐ No Change over tooling required. (automated)

P1.19 Human/Machine Interface (HMI) / Controller ☐ YES ☒ NO If yes, read detail below

☐ Computer – Touch screen: **n/a**
☐ Panel View – Touch screen: **n/a** Size / Model (if preferred): n/a
☐ Other (list): Alphanumeric display for status/temperature information
Vision display ☐YES ☐ NO
Keyboard & mouse drawer/ storage ☐YES ☐NO

Preferred cycle activation method: ☐OTB ☐Interlocked door activation ☐Automatic – MAS lines

All critical inputs or system variables are to be monitored by the PLC and visible on the HMI.

Equipment should aim to utilize robust programs and controllers that do not require license renewal plans.
An external Ethernet junction to the controller separate from the machine must be available so the PLC can be monitored, manipulated and verified independent of the equipment.

P1.20 HMI Screens programmed in English and Spanish ☐ YES ☒ NO If NO, read detail below

All equipment expected to be located in a Mexican Assembly site is expected to have HMI interface screens in Spanish. If HMI interface not programmed in Spanish, explain:

☐ Not located in a Spanish speaking region.

☒ Other rationale: No HMI.

P 1.21 Equipment Communication

Will the equipment require communication with any of the following systems? Please check all that apply.

	Kiosk ☐ YES ☒ NO	**MES** ☐ YES ☒ NO	**Proficient** ☐ YES ☒ NO	**TrakSys** ☐ YES ☒ NO
Connection Requirements	Include ethernet port for kiosk connection	Include ethernet port for MES connection	Include RS232 port for proficient	N/A

			connection.	
Procurement	Procurement of the kiosk is covered in this ERR? ☐ YES ☐ NO If NO, identify which ERR: _____	Will the MES station be included in the frame of this equipment? ☐ YES ☐ NO If NO, identify which ERR with MES station: _____	N/A	Will the TrakSys OPC server be installed in this equipment by the MAKE site? ☐ YES ☐ NO – Line includes kiosk that will contain local OPC server ☐ NO – Identify which ERR will contain the integrated OPC server: _____
Hardware Requirements	If procurement of the Kiosk is included in this ERR, will the kiosk connect with TrakSys OPC server? ☐ YES ☐ NO ☐ N/A If yes, include the following hardware (check all that apply): ☐ Location for OPC server within kiosk ☐ Additional ethernet port ☐ Switch for monitor/keyboard to be shared between kiosk and local OPC server.	If the MES station is included, which of the following hardware will be integrated into the equipment (check all that apply): ☐ Location for a computer/thin client ☐ Mounting location for a monitor Size: ☐ Keyboard drawer/storage ☐ Bar code reader and mount	What will be used to connect to proficient? ☐ Individual computer ☐ Kiosk.	If the line does not contain a kiosk, include the following hardware requirements: ☐ Space for switch that connects to OPC server. ☐ Space for an iPad If the OPC server will be installed on this equipment, include the additional hardware requirements (check all that apply): ☐ Mounting location for a monitor ☐ keyboard drawer/storage ☐ Switch to share monitor/keyboard with existing hardware
PLC Programming	N/A	N/A	N/A	Include a folder with tags related to: Batch, Part Number/Product Code, Good Unit Counter, Bad Unit Counter, Total Production Count, Reject by Reason Counter (Scrap), Failure by Reason Counter (Equipment Failure), Cycle Time (Avg. last 10 cycles), Machine Status (Running, Stopped, Setup, Inactive)

P1.22 Data Collection Required? ☐ YES ☒ NO If YES, read detail below

☐ PLC based ☐ PC based ☐ Other: n/a

What is the expected data output?

Data	Comments
n/a	n/a

P1.23 Software Development & Validation ☐ YES ☒ NO Read detail below.

Complete Appendix E for equipment utilizing software including off-the-shelf electronics containing software to determine the Software Validation Deliverables.

Rationale if selecting NO above:

☒ No Software or electronics containing software used in equipment
☐ Other rationale: n/a

P1.24 Factory Acceptance Testing

Factory acceptance testing defines per engineering study (WE0020) the initial verification testing activities that shall be carried out at the supplier, with satisfactory results, before the equipment may be approved for shipment. Run off is a shared responsibility between the person responsible for the equipment and the supplier.

Year 3 Single Shift Sample Size___n/a_____

FAT Sample Size Requirements

1. Total FAT Sample Size (Part Cycles + Dry Cycles) ≥ Yr 3 Single Shift Size
   1.1 If Yr 3 Single Shift Size ≤ 200, then Total FAT Sample Size (Part Cycles + Dry Cycles) ≥ 200
2. Part Cycles ≥ ½ x (Yr 3 Single Shift Size)

Will the above sample size requirements be met? ☐ YES ☐ NO If no, provide explanation/engineering rationale: n/a

If Equipment will run more than 1 product code, how many of each code will be included in the FAT? _____ ☒ N/A

FAT Criteria for Success
Listed below are common criteria for success for a Factory Acceptance Test. Indicate those that will be evaluated and provide target metrics if applicable:

☐ Equipment Downtime ____n/a_____
☐ Equipment Cycle Time _____n/a_____
☐ Changeover Time _____n/a_____
☐ Product Defects (MS) _____n/a_____
☒ Other ___equipment cycle_____n/a_____
☐ First Pass Yield_____n/a_____
☐ Capability Analysis _____n/a_____
☐ Safety & Ergo (WRAPS) Evaluation __n/a_____
☐ Software Evaluation_ _____n/a_____

P1.25 Training Requirements

It is expected that a reasonable amount of training and equipment development support will be accommodated within the equipment quote provided by supplier. The training proposed shall be disclosed within the equipment quote.

Supplier to provide training on Equipment/Fixture Operation? ☐ YES ☒ NO If no, explain: off the shelve equipment. Instructions included.

Supplier to provide development support of Equipment/Fixture Operation? ☐ YES ☒ NO If no, explain: n/a

P1.26 Supplier Production Line Start Up Support? ☐ YES ☒ NO If yes, read detail below

Minimum of 1 week of on-site support should be expected for any new line installation. Any phased install should allow for 1 week of on-site support during each phase.

Additional support can include remote support, conference calls, etc.

If applicable, specify the type of remote support software to be used for remote support of the equipment:

Scope of work and cost of this support to be included: ☐ Part of Equipment Quote ☐ Separate Quote:

Provide more explanation as needed (individuals requested, response time, conditions under which said support will be supplier's financial responsibility, etc.): n/a

P1.27 Supplier provided Shipment of Equipment? ☒ YES ☐ NO Read detail below

Ship Equipment to:

☐ Cincinnati: Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242, attention:

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

☐ Torres: Ethicon Endo-Surgery, (send to JVSF 420 Pan American Dr Suite-B-6, El Paso, Texas, 79907), attention:

☒ Independencia: Ethicon Endo-Surgery, (send to JVSF 420 Pan American Dr Suite-B-6, El Paso, Texas, 79907), attention: Omar Tovar/Javier Diaz

☐ Other (please specify): n/a

Provide unique shipping requirements as needed: n/a

P1.28 Supplier Provided Crating, Packaging, Cert of Origin, Photography, Uncrating and Installation?

Equipment must be crated for shipment using Heat Treated Crates/Pallets/Solid wood (reference WE0576).

Supplier to provide crating and packaging? ☒ YES ☐ NO, explain how equipment is prepared for shipment:

Per WE0373, in addition to including FMWE0376.1 with the equipment to be shipped, certificates of origin and photography must be included for all articles being shipped:

Supplier to provide nafta certificate of origin for all articles being shipped? (reference WE001160) ☒ YES ☐ NO

Supplier to provide photography of all articles being shipped? (reference WE0373) ☐ YES ☒ NO

Supplier to provide uncrating and installation at final make site? ☐ YES ☒ NO

All Equipment shall be packed, crated, skidded or otherwise secured to assure acceptance by common Carrier for safe transportation. All loose boxes shall be clearly marked and consolidated onto pallets or into larger boxes. The Equipment shall be preserved according to best commercial practice and adequately protected from physical damage, contamination and corrosion during transit.

P1.29 Project Schedule

Supplier is responsible for creating, maintaining, and providing a project schedule.

Below are the minimum elements to be included in the Equipment Project Schedule (With requested Completion Dates):

Indicate the requested Project Update frequency

☐ Weekly ☐ Bi-Weekly ☐ Monthly ☐ At Schedule Milestones ☒ Other, explain: Off the shelf equipment.

*Note – Weekly meetings are encouraged to maintain communication. Frequency may be updated depending on stage, state and urgency of project.

P1.30 Major Project Milestones		
Milestone	**Target Completion Date**	**Owner**
Quote Due Date	Aug 2019	Supplier
PO Issuance	Aug 2019	Ethicon
Product Design Freeze	n/a	Ethicon
Acceptance Test Complete	n/a	Supplier / Ethicon
Equipment Transfer to Mfg Site	Jan 2020	Supplier / Ethicon

P1.31 Equipment Design Change Control

The cost and time impact of any significant requested project scope changes should be disclosed before implementing the change. All changes must be agreed upon by both Ethicon and the Supplier. It is recommended to capture these changes in revisions of this document.

To address significant cost impacts, Purchase Order update/s or new Purchase Order issuance should be considered. The associated ETHICON Buyer/Planner and PM Product Manager should be made aware of the cost impacts in a timely manner.

All software changes after the validation and software upload to Epicenter shall require change control administrated via CP0150. The software is validated exclusively in the state defined within the associated software validation.

P1.32 Warranty Scope and Duration

Subject to the Warranty terms set forth below, Seller warrants that the products furnished hereunder will be free from defects for a period of one year from the date of manufacture and will be produced in accordance with the specifications received from the buyer as defined in the equipment requirements document and in accordance with the terms and conditions prescribed in the purchase order.

Any items, materials or software which fails to perform as required by this specification or deteriorate excessively shall be considered defective under this warranty.

For purposes of warranty duration, the date of manufacture shall be defined as the date of the final acceptance of the equipment as agreed to and documented by both the equipment supplier and the individual responsible for development of this equipment.

P1.33 Warranty Obligation

SELLER will repair or replace any product that is found to be defective; including materials, workmanship, or failure to conform to specifications received from Buyer. Duration is one year from manufacture, with the following limitations and conditions ("Warranty"):

a. Written notice of a claim must be delivered to Seller within thirty (30) days of defect discovery. If not received within thirty (30) days, claim shall be deemed waived by the Buyer and in every case this written notice must be provided within one (1) year from the date of manufacture of the product.
b. Seller must be given a reasonable opportunity to investigate the product and claimed defect. Buyer will preserve all products for a reasonable time to permit proper testing and investigation.
c. Final determination as to whether or not a product is defective rests with Seller. Prior to returning any product to Seller, approval must first be obtained from Seller. If the product was damaged in transit to Seller, the claim must be filed with the carrier.
d. Notwithstanding anything to the contrary herein, all parts and materials purchased by Seller from a manufacturer, seller or supplier and subsequently incorporated into a system, piece of equipment or tooling will carry the manufacturer's standard warranty. Seller assigns to the Buyer all rights and claims acquired against seller, supplier or manufacturers of said parts and materials. Buyer shall have no rights for warranty or any other claims against Seller for any such parts or materials.
e. THIS WARRANTY DOES NOT COVER LOSS, DAMAGE OR DEFECTS RESULTING FROM IMPROPER OR INADEQUATE USE BY THE BUYER OR UNAUTHORIZED MODIFICATION OR MISUSE OF THE PRODUCTS. The Buyer has the obligation to

maintain and operate the provided System, piece of Equipment or Tooling in accordance with Seller recommendations. Seller recommended and other reasonable periodic maintenance shall be appropriately completed by qualified technicians. Failure to meet the forgoing will result in the Warranty being rendered null and void.

f. With approval from Seller, ETHICON may perform emergency repairs without voiding the warranty. In the case of emergency repairs, the Seller shall be responsible only for the cost of materials and purchased parts used in the repair.

g. Software for a system or piece of equipment shall be warranted for a period of (90) ninety days from final Buyer acceptance. Software changes will require agreement between buyer and seller during the warranty period.

P1.34 Recommended Payment Milestones

Recommended supplier invoice schedule, upon completion of the Project Milestones listed below, as described in the purchase order in accordance with WW330 (Policy on Funds Advanced to Third Parties):

Milestone	Milestone Description
1	Invoiced Upon P.O. Issuance
2	Invoiced Upon Final Design Approval (Phase 2 ERR approved) / Begin Shop Fabrication
3	Invoiced after successful FAT
4	Receive / Installation complete and equipment ready for startup
5	Invoiced after successful Site Acceptance
6	Invoiced upon completion of Equipment Documentation (Drawings, Software, Manuals, etc.)

P1.35 Equipment Kickoff Meeting

Equipment Kickoff Meeting
The equipment kickoff meeting shall be completed after Phase 1 of the ERR is filled out by the Ethicon Equipment/Development Engineer, but prior to quote issuance from the supplier. The purpose of this meeting is for Ethicon and the Supplier to align on requirements/specifications defined in Phase 1, such that the equipment can be properly quoted.

Equipment Kickoff Meeting to be held prior to quote issuance? ☐ YES ☐ NO If no, explain:

Once Phase I is completed, Upload the following documents to EPIcenter. If additional information is available at this time proceed to Phase II prior to quoting.

P1.36 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	N/A	Assembly Line Layout

P1.37 Phase I Approval (Indicate approval status of this revision)
(Reference WE0179 Appendix I P1.37 for Phase I Approval Matrix)

Prerequisite for PO kickoff

☐ Due to the maturity of the equipment requirements, Phase 2 of this ERR has also been completed. Signature matrix in section P2.21 is required for this revision of the ERR. This ERR will be revised after the Equipment Design Review and the appropriate supporting documentation uploaded to EPIcenter. N/A the Name and User ID blanks below except for capital owner, if required in addition to P2.21 signatures.

Function	Name	User I.D.	Signature/Date
n/a	n/a	n/a	eSig in EPICENTER

Phase 2.0 Design and Fabrication

Phase 2 of this ERR shall be completed after the equipment design review has been conducted with the supplier as indicated by selecting “Phase 2 Post Design Review” in the ERR Phase title block of this document. If ERR Phase in the tile block of this document is indicated as “Phase 2 Pre-Design Review”, complete sections P1- P2-20.

P2.1 Component / Sub-Assembly Identification and Status:	☐ Updated ☒ No Change
See 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.	

P2.2 Product Requirements (description of the process exclusive to the equipment within this requirement)	☐ Updated ☒ No Change
See Appendix B for Product Requirements. Any additions or modifications to the product requirements since the initial revision of this ERR shall be documented in Appendix B.	

P2.3 Process Description (description of the process exclusive to the equipment within this requirement)	☐ Updated ☒ No Change
See Appendix C for SIPOC. If not already, all sections of SIPOC should be filled out during this phase. Any additions or modifications to the SIPOC since the initial revision of this ERR shall be documented in Section C1.1 of Appendix C.	

P2.4 Product/Process Assumptions	☐ Updated ☒ No Change
Any modifications to the product/process assumptions since the initial revision of this ERR shall be documented in section P1.7.	

2.5 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	
2.6 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.	

P2.7 Process Failure Modes Effects Analysis (PFMEA)

A PFMEA is intended to communicate the risks identified and associated with this operation or previous operations for which the equipment is designed to mitigate. As failure modes are encountered during the development of the equipment and process, it is recommended to update the PFMEA and corresponding equipment design inputs. Appropriate mitigations should be agreed to between the responsible engineer and the equipment designer during the equipment development.

☐ A PFMEA is available for review and to be provided with this ERR.

PFMEA Document #	Revision (if draft, indicate draft date)	Product code(s) in scope of the PFMEA
n/a	n/a	n/a

☐ A preliminary PFMEA is not available for this revision. Below are the potential process failures modes identified, the effect of the failures on the device, the harm severity level, and suggested mitigations in order to manage the risk at this at this process.

Potential Failure Mode	Process Cause	Effect of the failure on the device in process.	Harm Severity Level	Suggested Mitigation/s
n/a	n/a	n/a	n/a	n/a

☒ N/A – This equipment is not intended to mitigate any known PFMEA risks.

P2.8 Equipment Failure Mode and Effects Analysis

Per section P2.7 PFMEA when the equipment is responsible for detection harm Severity S5, S4, S3 there shall be an EFMEA performed by the supplier and responsible engineer (guidance template FRM003587, or similar may be used for this analysis).

Is an E-FMEA required?

☐ YES – Reference WE0179, WE0222 & FRM003587. The analysis may lead to additional controls needing to be put in place and/or a management review if risk remains high after equipment design efforts have been exhausted.

☒ NO – This equipment is not responsible for detection of (Severity S5, S4, S3) PFMEA failure modes.

☐ NO – Other rationale:

☐ TBD – To be determined at a follow-up revision when preliminary PFMEA is available.

P2.9 Control Plan

A Control Plan is intended to summarize the systems used in minimizing and controlling process variation to the appropriate level of control with the level of risk to the end user or patient. As process controls are defined during the development of the equipment and process it is recommended to update the control plan and corresponding equipment design. Appropriate controls should be agreed upon between the engineer responsible for the equipment, quality, and the equipment supplier during the equipment development.

☐ A Control Plan is available for review and to be provided with this ERR. (Reference FRM000486)

Control Plan Document #	Revision (if draft, indicate draft date)	Product code(s) in scope of the CP
n/a	n/a	n/a

☐ This equipment is for a new process under development and no assembly control plan is available for review.

☐ The control plan **is** anticipated to be available for review within the timeframe of the equipment development, once the process has matured. The systems used in minimizing and controlling process variation as known for this revision of the ERR are shown in the table below.

☒ The control plan **is not** anticipated to be available for review within the timeframe of the equipment development. The method utilized to ensure all necessary checks/inspections have been captured within the equipment requirements is as follows:

Critical Requirement	Product/Process Specification	Potential Control Method	Frequency
Temperature	tbd	HVAC temperature sensor	100%

☐ This equipment does not have a requirement for process control.

P2.10 Gages / Calibration	☒ Appendix D completed

Reference Appendix D for Gages and Calibration. Identify for each measurement the type of gage utilized, the expected calibration range, and status. Equipment shall be intended to use normalized or standard methods of calibration with available off the shelf measurement methods whenever possible.

P2.11 Gage R&R studies	☒ Appendix D completed

Reference Appendix D for Gage R&R strategy. Identify the strategy for each gage R&R study to be performed.

P2.12 Gage Compatibility	☒ Appendix D completed

Reference Appendix D for Gage compatibility requirements.

P2.13 Equipment Reliability	☒ Appendix D completed

Reference Appendix D for Equipment Reliability requirements.

P2.14 Special Utilities required? ☐ Yes ☒ No If yes, read detail below

Reference WE0725 for additional information regarding expected design standards by assembly facility. Standard utilities for equipment operation are expected to be provided by supplier. Specific, customer required, utilities should be explained below:

Utility	Details
n/a	n/a

P2.15 Ethicon Provided Materials required? ☒ Yes ☐ No If yes, read detail below

Describe the provided equipment needed and intentions for documentation (separate E#, separate G#, detailed within proposed Equipment drawing):

See Appendix A

P2.16 Recommended Software Modes

Modes	Required (Y/N)	Detail
Auto Mode	Y	Capability to increase/decrease temperature automatically according to defined values.
Manual Mode	Y	Capability to increase/decrease temperature manually.
Setup Mode	N	n/a
More	N	n/a
Variable Input Mode	N	n/a

Dry Cycle Mode	N	n/a
FGQA Run Mode	N	n/a
GRR Mode	N	n/a
Calibration Mode	N	n/a
Preventative Maintenance Mode	N	n/a
Purge Mode	N	n/a

P2.17 Major Project Milestones

Milestone	Expectation	Target Completion Date	Owner
Device / Component Models & Drawings Available	N/A	n/a	Ethicon
Equipment FMEA (E-FMEA), if applicable	FRM003587 or similar (when applicable)	n/a	Supplier
Equipment Design Review	FRM003588 (when applicable)	Dec 2019	Ethicon
Software Design Review	Software Design Review Checklist from FRM003589 (when applicable)	n/a	Supplier/Ethicon
Equipment Fabrication Completion / First Article testing	N/A	n/a	Supplier/Ethicon
Equipment Characterization	Engineering Study (FMWE0020.1)	n/a	Ethicon
Acceptance Test Complete	Engineering Study (FMWE0020.1)	n/a	Ethicon
Equipment Transfer to Mfg Site	N/A	Jan 2020	Supplier/Ethicon
Equipment Drawings & Models	G10011	Jan 2020	Supplier
Other Equipment Documentation (Manuals, Spare Parts, etc.)	FRM003591	Jan 2020	Supplier/Ethicon

P2.18 Equipment Design Review ☐ Completed ☒ Phase 2 Pre-design review

Equipment design review shall be completed prior to the post design review revision of the ERR. Design Review Checklist FRM003588 shall be completed and uploaded to EPIcenter.

P2.19 Software Development & Validation Read detail below. ☐ Updated ☒ No Change

Review Appendix E to confirm the information. (For example, change in equipment software complexity or risk detection profile)

Once Phase II is completed, Upload the following documents to EPIcenter.

P2.20 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**
Attachment I	N/A	Assembly Line Layout
n/a	FMWE0222.4	Applicable Lines of Process FMEA (if shared via attachment, otherwise "N/A")
n/a	FRM003587 or similar.	Equipment FMEA
n/a	FRM000486	Applicable Lines of Control Plan (if shared via attachment, otherwise "N/A")
n/a	FRM003588	Equipment Design Review Checklist

P2.21 Phase 2 Approval (Indicate approval status of this revision)

(Reference WE0179 Appendix I P2.21 for Approval Matrix.)

Prerequisite for equipment fabrication

☐ Phase 1& 2 approval prior to Equipment Design Review. ERR shall be revised after Equipment Design Review to include all attachments in P2.20 as indicated.

☐ Phase 2 approval after Equipment Design Review and all documents in P2.20 uploaded to EPIcenter.

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

Appendix A Component / Sub Assembly Identification and Status

A1.1 Component / Sub-Assembly Identification and Status:

Part Name	Drawing number	Drawing Rev. (if applicable)	Image of Part	Comments
0009	tbd	tbd	tbd	tbd
0012	tbd	tbd	tbd	tbd
0012A	tbd	tbd	tbd	tbd
0012AM	tbd	tbd	tbd	tbd
0012AMP	tbd	tbd	tbd	tbd
0012AP	tbd	tbd	tbd	tbd
0012M	tbd	tbd	tbd	tbd
0012MD	tbd	tbd	tbd	tbd
0013	tbd	tbd	tbd	tbd
0012C	tbd	tbd	tbd	tbd
0013M	tbd	tbd	tbd	tbd
0022S	tbd	tbd	tbd	tbd
0014	tbd	tbd	tbd	tbd
0021S	tbd	tbd	tbd	tbd
0014A	tbd	tbd	tbd	tbd
0020S	tbd	tbd	tbd	tbd
0014AM	tbd	tbd	tbd	tbd
0014AMD	tbd	tbd	tbd	tbd
0014AMP	tbd	tbd	tbd	tbd
0019S	tbd	tbd	tbd	tbd
0014M	tbd	tbd	tbd	tbd
0100S	tbd	tbd	tbd	tbd
0015	tbd	tbd	tbd	tbd
0016	tbd	tbd	tbd	tbd
0016A	tbd	tbd	tbd	tbd
0016M	tbd	tbd	tbd	tbd
0017	tbd	tbd	tbd	tbd
0018	tbd	tbd	tbd	tbd
0018C	tbd	tbd	tbd	tbd
0019	tbd	tbd	tbd	tbd
0019L	tbd	tbd	tbd	tbd
0020	tbd	tbd	tbd	tbd
0020L	tbd	tbd	tbd	tbd
0029	tbd	tbd	tbd	tbd
0100LS	tbd	tbd	tbd	tbd
0021	tbd	tbd	tbd	tbd
0021L	tbd	tbd	tbd	tbd
0021LS	tbd	tbd	tbd	tbd
0020LS	tbd	tbd	tbd	tbd
0022	tbd	tbd	tbd	tbd

0019LS	tbd	tbd	tbd	tbd
0024	tbd	tbd	tbd	tbd
0018CS	tbd	tbd	tbd	tbd
0026S	tbd	tbd	tbd	tbd
0028	tbd	tbd	tbd	tbd
0028M	tbd	tbd	tbd	tbd
0012P	tbd	tbd	tbd	tbd
0029M	tbd	tbd	tbd	tbd
0100	tbd	tbd	tbd	tbd
0100L	tbd	tbd	tbd	tbd
0014AP	tbd	tbd	tbd	tbd
0014P	tbd	tbd	tbd	tbd
0105S	tbd	tbd	tbd	tbd
0113	tbd	tbd	tbd	tbd
0113A	tbd	tbd	tbd	tbd
0113M	tbd	tbd	tbd	tbd
0012MP	tbd	tbd	tbd	tbd
0118	tbd	tbd	tbd	tbd
0014MP	tbd	tbd	tbd	tbd
0118A	tbd	tbd	tbd	tbd
0119	tbd	tbd	tbd	tbd
0119A	tbd	tbd	tbd	tbd
0120	tbd	tbd	tbd	tbd
0121	tbd	tbd	tbd	tbd
0300	tbd	tbd	tbd	tbd
0312	tbd	tbd	tbd	tbd
0312A	tbd	tbd	tbd	tbd
0312AM	tbd	tbd	tbd	tbd
0312M	tbd	tbd	tbd	tbd
0313	tbd	tbd	tbd	tbd
0313M	tbd	tbd	tbd	tbd
0314	tbd	tbd	tbd	tbd
0314A	tbd	tbd	tbd	tbd
0314M	tbd	tbd	tbd	tbd
0315	tbd	tbd	tbd	tbd
0316	tbd	tbd	tbd	tbd
0316A	tbd	tbd	tbd	tbd
0316AM	tbd	tbd	tbd	tbd
0316M	tbd	tbd	tbd	tbd
0600	tbd	tbd	tbd	tbd
0600M	tbd	tbd	tbd	tbd
0605	tbd	tbd	tbd	tbd
0618	tbd	tbd	tbd	tbd
0619	tbd	tbd	tbd	tbd
0620	tbd	tbd	tbd	tbd
0620M	tbd	tbd	tbd	tbd

0621	tbd	tbd	tbd	tbd
0621M	tbd	tbd	tbd	tbd
0690	tbd	tbd	tbd	tbd
0690S	tbd	tbd	tbd	tbd
0695	tbd	tbd	tbd	tbd
0695S	tbd	tbd	tbd	tbd

Method of component revision control / notification: n/a

Appendix B Product Requirements

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.

Design Requirements Workbook Document #	Revision (if draft, indicate draft date)	Product code(s) in scope of the workbook	Location of Relevant Requirements
n/a	**n/a**	**n/a**	☐ Included with ERR Package. ☐ included in table below ☐ Other:_____n/a_____ ☐ 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.

Requirement 1:				
Requirement Name	**Requirement**	**Requirement Number**	**Product Code(s)**	**Defect Class**
n/a	n/a	n/a	n/a	n/a

Appendix C SIPOC

C1.1 Process Description - SIPOC Diagram of proposed process (explicit description of the process exclusive to the equipment within this requirement	
SUPPLIERS (RESOURCE PROVIDER)	• Coating area.
INPUT (INPUT TO THE PROCESS)	• Water. • Liquid cooling supply • Recently coated substrates.
PROCESS (PROCESS STEPS)	• Place recently coated substrates into drying enclosure. • HVAC will provide controlled temperature. • Humidifier will provide controlled humidity.
OUTPUT (OUTPUT FROM THE PROCESS)	• Dried up coated substrates
CUSTOMER (RECEIVE OUTPUT FROM THE PROCESS)	• Curing oven.

Appendix D Gages

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
1	temperature	tbd	tbd	critical

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)
n/a	n/a	n/a	n/a

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)
n/a	n/a

☒ 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: n/a

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**
n/a	n/a	n/a	n/a

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: n/a

Appendix E Software Development and Validation

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