

# QiG SCS (Algostim) IPG Master Process Validation Plan

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| Revision | Description                 | Approved By   | Date     |
|----------|-----------------------------|---------------|----------|
| A        | Initial Release             | G Routh       | 1-10-12  |
| B        | Processes Update            | W Omer        | 10-17-13 |
| C        | Part/Process Number Updates | <i>W Omer</i> | 11-14-13 |

## Plan Review Sign-Off

|                                       | Name (printed)   | Signature            | Date        |
|---------------------------------------|------------------|----------------------|-------------|
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| Regulatory                            | Doug Atkins      | <i>Doug Atkins</i>   | 10-22-2013  |

ORIGINAL

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## 1.0 PURPOSE

The purpose of this Master Validation Plan is to provide an objective guide to assess the activities pertaining to Tool, Install, Operational, Performance, and Software Qualification performed to ensure proper process validation planning.

## 2.0 SCOPE

### 2.1 IPG manufactured component and subassemblies produced on manufacturing line

| Part Number | Description                           |
|-------------|---------------------------------------|
| 1011003     | SCS, Lid Side Sub-Assembly            |
| 1011004     | SCS, Feed Thru Side Sub-Assembly      |
| 1005152     | SCS, 3X8 Stacker Sub Assembly         |
| 1005151     | SCS, 2X12 Stacker Sub Assembly        |
| 1012954     | SCS, ID Tag Sub Assembly              |
| 1012946     | SCS, 3X8 Header Stacker Sub Assembly  |
| 1012947     | SCS, 2X12 Header Stacker Sub Assembly |
| 1005468     | SCS, 2412 Model IPG                   |
| 1005322     | SCS, 2408 Model IPG                   |
| 1007833-001 | Sterile IPG, Model 2408               |
| 1007833-002 | Sterile IPG, Model 2412               |

### 2.2 IPG Final Packed Kit model numbers

| Part Number | Description              |
|-------------|--------------------------|
| 1009799-001 | Final Packaged IPG, 2408 |
| 1009799-002 | Final Packaged IPG, 2412 |

## 3.0 REFERENCE DOCUMENTS

| Document Number | Document Title  |
|-----------------|---|
| 1000056         | Product Development SOP                                     |
| 1000098         | Process Validation SOP                                      |
| 1000064         | Risk Management SOP   |
| 1004467         | IPG PFMEA   |
| MEPL 0068       | QiG IPG Design Transfer Document                            |
| 1012376         | QiG SCS System (Algostim) Design & Development Plan         |
| 1005916         | IPG Quality Plan / Component Qualifications                 |
| 1005268         | QIG - 3x8 Header Form Component Qual Plan                   |
| 1005269         | Triple Stack End Cap Molded Component Qualification Plan    |
| 1005266         | Triple One Sided Plastic Stacker Molding Qualification Plan |
| 1005270         | QIG - 2x12 Header Form Component Qual Plan                  |
| 1005272         | Double Stack End Cap Molding Qualification Plan             |
| 1005271         | Double Plastic Stacker Molding Qualification Plan           |
| 1013136         | Algostim IPG Training Certification Assessment              |

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|-----------|--|
| QAQP 0093 | Algostim EtO Sterilization Strategy and Validation Plan        |
| 1013324   | Master Process Validation Plan, Label Generation AlgoStim™ SCS |

## 4.0 DEFINITION

PFMEA: Process Failure Modes and Effects Analysis  
MVP: Master Validation Plan  
MVR: Master Validation Report  
IQ: Equipment (Installation and Operational) Qualification  
TQ: Tool Qualification  
OQ: Process Operational Qualification  
PQ: Process Performance Qualification  
SQ: Software Qualification  
TMV: Test Method Validation  
Cal: Calibration  
PPQ: Product Performance Qualification  
PM: Preventative Maintenance  
R&I: Receiving and Inspection  
IP: Inspection Procedure  
MP: Manufacturing Process

## 5.0 BACKGROUND

Greatbatch Medical is responsible for the manufacturing of the Algostim SCS IPG product. The development of this design was completed by the QiG Group, LLC. This design is being transferred to Greatbatch Medical at the point of process scale-up and Validation.

## 6.0 IN-PROCESS QUALITY ASSURANCE MEASURES

Non-verifiable processes will be validated based on the calculated risk in the Process FMEA. Items listed in the Process FMEA that are verifiable will not be validated but will be 100% inspected unless otherwise noted in this plan.

In-process quality assurance measures will be evaluated as part of the Process FMEA to determine if controls provide acceptable risk level. Those controls that do not provide acceptable risk level will be mitigated. The mitigations will be completed and routed for approval on or before the approval of the Master Validation Report; the Process FMEA will be revised to include any changes.

Purchased components and corresponding component qualifications are located in the Quality Plan (See Reference Documents).

## 7.0 VALIDATION SAMPLE SIZE RATIONALE

### 7.1 Sample Plan and Data Analysis

Sample sizes and data analysis will be individually defined with the qualification protocols and will follow SOP 42120.

## 8.0 MATERIALS/COMPONENTS

### 8.1 Material/Component Deviations

Specific part numbers for all material/component deviations will be included in their respected process OQ/PQ protocols.

- **Feedthrough Welding for Algostim IPG**  
FT welding validation will be performed using FT's from two different manufacturing sites within Greatbatch Medical.

FT Welding OQ – Feed throughs used for operational qualification will be manufactured parts from Greatbatch Medical Western New York and will not have filters attached to the FT (Also known as “unfiltered” feed throughs). The filter is not required to assess the feed through flange to IPG shield welding.

FT Welding PQ – Feed throughs used for performance qualification will be manufactured at Greatbatch Medical Mexico and will include filters.

No changes to processes, materials, or design will be made when receiving process validated feed throughs from the Greatbatch Medical Mexico facility.

- **IPG PCB to Feedthrough Solder Attach**  
PCB Soldering validation will be performed with bare PCB's populated with kovlar blocks.

The soldering operation is performed at the flex portion of the PCB, which is the same on bare and and populated PCBs. The fully populated boards are not required to assess the PCB to FT Soldering process.

- **Battery Attach for Algostim IPG**  
Battery attach welding validation will be performed with Mock Batteries and bare PCB's populated with kovlar blocks.

The battery attach welding process bonds the battery terminal to the Kovar blocks mounted to the PCB. The validation will be performed using bare PCBs that are populated using the same Kovar blocks. Fully populated boards are not required to assess the battery attach welding process.

Mock batteries will be used since they are identical to real batteries in shape, size and materials; except for internal make up. There is no interaction between the internal components of the battery and welded battery terminal. Real batteries are not required to assess the battery attach welding process.

- **SCS IPG Coil Attach**  
Coil Soldering validation will be performed using bare PCB's populated with Kovar blocks.

The coil soldering process bonds the tinned coil wire terminations to the Kovar blocks mounted to the PCB. The validation will be performed using PCBs that are populated using the same Kovar blocks and mounting process as in fully populated boards. The fully populated boards are not required to assess the coil attach process.

## 9.0 SEQUENCE OF OPERATIONS

Reference document number 1013335 Algostim IPG Manufacturing Flow Chart.

## 10.0 PRODUCT PERFORMANCE QUALIFICATIONS

Product Performance will be defined and reported within separate documents and referenced within the Master Validation Report.

## 11.0 TEST METHOD QUALIFICATION/VALIDATIONS

Test methods used to assess validated process outputs will be qualified either through test method qualification, validation, and/or training certification.

- Destructive test method validations – Require test method validations to be performed.
  - Deviations from the acceptance criteria for variable studies (Destructive) are permitted in situations where the capability index of the parameter(s) under investigation is greater or equal to 2.0, because this implies that the instrument/gage is not adding excessive variability to the study.
- Non-destructive variable data - Require test method validations to be performed.
  - Deviations from the acceptance criteria for variable studies (Non-destructive) are permitted in situations where the capability index of the parameter(s) under investigation is greater or equal to 2.0, because this implies that the instrument/gage is not adding excessive variability to the study.
- Non-destructive, attribute data -Attribute test methods that are part of the manufacturing processes will be qualified through the training certification program. Reference training certification assessment 1013136. An attribute test method validation will be conducted only on attribute test methods that are not part of the certification program.

## 12.0 PROCESS CHARACTERIZATION REPORTS

| Report # | Title  |
|----------|--|
| 1013032  | Algostim IPG L-Tab Laser Weld Process Characterization Report          |
| 1013033  | Algostim IPG FeedThrough Laser Weld Process Characterization Report    |
| 1013035  | Algostim IPG Weld Band Laser Weld Process Characterization Report      |
| 1013036  | Algostim IPG Battery Attach Laser Weld Process Characterization Report |
| 1013037  | Algostim IPG Device Laser Tack Weld Process Characterization Report    |
| 1013038  | Algostim IPG Device Laser Seam Weld Process Characterization Report    |
| 1013039  | Algostim IPG Lead Frame Laser Weld Process Characterization Report     |
| 1013174  | Algostim Bake Cycle Process Characterization Report                    |
| 1013175  | Algostim Bead Blasting Process Characterization Report                 |
| 1013176  | Algostim Leak Testing Process Characterization Report                  |
| 1013184  | Algostim IPG Laser Marking Process Characterization Report             |
| 1013185  | Algostim IPG PCB to Feedthrough Attach Process Characterization Report |
| 1013186  | Algostim IPG Thermistor to Can Bonding Process Characterization Report |

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|---------|--|
| 1013187 | Algostim IPG ID Tag Attach Process Characterization Report                               |
| 1013188 | Algostim IPG Coil Attach Process Characterization Report                                 |
| 1007964 | Tray Sealing Process Characterization for SCS IPG Sterile Packaging                      |
| 1010426 | Silicone dispensing into molded stackers for SCS Model 2408 and 2412 devices             |
| 1009052 | IPG to Polysulfone molded Header Bonding Characterization                                |
| 1013204 | MED-6210 Silicone cure study for final back fill of Algostim Model 2408 and 2412 devices |
| 1013205 | Algostim Header/Silicone Backfill characterization                                       |
| 1013206 | MED-6210 silicone De-aeration characterization   |





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## 13.0 APPENDIX

### 13.1 Planning Matrix

| Process Step                   | Validation Scope  |                               |        |    |    |    |                                    |  |  |  | Rationale |
|--------------------------------|---|-------------------------------|--------|----|----|----|------------------------------------|--|--|--|-----------|
|                                | Key:<br>xxx.xxx - Document #s listed indicate completion of qualification activity and/or leverage of historical data |                               |        |    |    |    |                                    |  |  |  |           |
|                                | Equipment ID #  | Equipment Description/ Spec # | IQ/ TQ | OQ | PQ | SQ | Test Method Qualification Approach | Risk Level   | Requirement  |  |           |
| Feed Through Side Sub Assembly |   |                               |        |    |    |    |                                    |  |  |  |           |
| L-Tab Welding<br><br>1010547   | 12-00396  | ILT 1500 Fiber Laser          | X      | X  | X  | X  |                                    | Training certification assessment 1013136  | Validated Requirement: Tensile<br><br>Verified Requirements: Visual Criteria<br><br>Validated output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement at challenge process parameters as well as across multiple setups/material lots where applicable. Tensile strength will be our validated output. |  |           |
|                                | 1010689   | L-Tab Welding Fixture         | X      |    |    |    |                                    | Not Required: Capability index greater than or equal to 2.0<br><br>Reference 1013032 |  |  |           |
|                                | 12-00138  | Chatillon Tensile Tester      | X      |    |    |    |                                    |  |  |  |           |



|                                 |  |   |     |     |     |     |             |     |  |
|---------------------------------|--|---|-----|-----|-----|-----|-------------|-----|--|
| Feed Through Welding<br>1010548 | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>11-00266<br>12-00403<br>12-00404<br>13-00196<br>13-00234<br>13-00235 | Ophir Power Meter and SH to USB Interface | --- | --- | --- | --- | Calibration |     |  |
|                                 | 12-00396   | ILT 1500 Fiber Laser                      | X   |     |     |     |             |     |  |
|                                 | 1011592  | FT Welding Fixture                        | X   | X   | X   |     |             |     |  |
|                                 | TBD  | Cross Section Equip                       | X   |     |     |     |             |     |  |
|                                 | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>11-00266<br>12-00403<br>12-00404                                     | Ophir Power Meter and SH to USB Interface | -   | --- | --- | --- | Calibration | Low |  |
|                                 |  |   |     |     |     |     |             |     |  |
|                                 |  |   |     |     |     |     |             |     |  |
|                                 |  |   |     |     |     |     |             |     |  |
|                                 |  |   |     |     |     |     |             |     |  |
|                                 |  |   |     |     |     |     |             |     |  |
|                                 |  |   |     |     |     |     |             |     | Validated output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement at challenge process parameters as well as across multiple setups/material lots where applicable. Weld penetration will be our validated output. |



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| Weld Band<br>Welding<br>1010550 | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>11-00266<br>12-00403<br>12-00404<br>13-00196<br>13-00234<br>13-00235 | Ophir Power<br>Meter and SH<br>to USB<br>Interface | --- | --- | --- | --- | Calibration  | Low | Verified<br>Requirements:<br>Visual Criteria | Output is and will be 100% verified and<br>as a result does not require an OQ/PQ to<br>be performed. However, OQ will be<br>performed to define production process<br>windows for variable inputs. |
|                                 | 12-00395   | ILT 1500 Fiber<br>Laser                            | X   |     | X   |     |  |     |  |  |
|                                 | 1012145  | Welding<br>Fixture                                 | X   |     |     |     | Training<br>certification<br>assessment<br>1013136 |     |  |  |
|                                 | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>11-00266   | Ophir Power<br>Meter and SH<br>to USB<br>Interface | -   |     |     |     | Calibration  |     |  |  |

|  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|-----|---|------------|--|--|--|
|  | 12-00403<br>12-00404<br>13-00196<br>13-00234<br>13-00235 |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
| Graphite Sheet and Battery Insulator Attachment<br>1010895           | 1012175  | Attach Fixture Assembly                     | X |  |  |  |  |  |  |  |  |  |  |  |     | Training certification assessment 1013136 | Acceptable | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. |  |
| Stacker Sub Assembly   |  |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
| Stacker Assy 1005202<br><br>Inspection and Set Screw Install 1010887 | 12-00411,<br>13-00406 /<br>12-00412,<br>13-00452         | Assembly Tooling – Robot, Press and Stacker | X |  |  |  |  |  |  |  |  |  |  |  |     | Training certification assessment 1013136 | Low        | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. |  |
|  | 12-00390<br>12-00389                                     | Dispensing Robot with EFD                   | X |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
|  | 12-00544<br>12-00545                                     | CB Press                                    | X |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
|  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
|  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
|  | 12-00558   | Seal Inspection                             | X |  |  |  |  |  |  |  |  |  |  |  | TMV |   |            |  |  |  |
| ID Tag Sub Assembly  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |     |   |            |  |  |  |
| ID Tag Attach<br>1012549   | 12-00697   | EFD Dispenser                               | X |  |  |  |  |  |  |  |  |  |  |  |     | Training certification assessment 1013136 | Acceptable | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. |  |

| Header Stacker Sub Assembly             |  |                                    |   |     |     |     |     |     |             |   |            |  |  |
|---|--|------------------------------------|---|-----|-----|-----|-----|-----|-------------|---|------------|--|--|
| Attach Septum to Header<br>1011489      | 12-00388<br>13-00219   | EFD Dispenser                      | X | --- | --- | --- | --- | --- | ---         | Training certification assessment 1013136 | Low        | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed.   |
|   | 12-00388<br>13-00219   | EFD Dispenser                      | X | --- | --- | --- | --- | --- | ---         | Training certification assessment 1013136 | Low        | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed.   |
| IPG Finished Assembly                   |  |                                    |   |     |     |     |     |     |             |   |            |  |  |
| IPG Circuit Board Inspection<br>1009906 | X  | Electrical Test 1A/1B              | X | X   | X   | X   | X   | X   | X           | TMV                                       | Low        | Verified Requirements: Electrical      | 100% electrical verification/inspection performed in receiving inspection.   |
|   | X  | Test Fixture                       | X |     |     |     |     |     |             |   |            |  |  |
| IPG Laser Marking<br>1010786            | 12-00079   | Keyence                            | X | X   |     |     |     |     | X           | Training certification assessment 1013136 | Acceptable | Verified Requirements: Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. However, OQ will be performed to define production process windows for variable inputs. |
|   | 1010787<br>1010788   | Marking Fixtures                   | X |     |     |     |     |     |             |   |            |  |  |
|   | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>13-00230 | Ophir Power Meter and Nova Display |   |     |     |     |     |     | Calibration |   |            |  |  |
|   |  |                                    |   |     |     |     |     |     |             |   |            |  |  |
|   |  |                                    |   |     |     |     |     |     |             |   |            |  |  |
|   | 12-00042   | EFD Dispenser                      | X | --- | X   | --- | --- | --- | ---         | Training                                  | Low        | Validated                              | Output is and will be 100% verified and  |



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|---|--|--|-----|--|-----|--|-----|-----|--|---|---|
| PCB to<br>Feedthrough<br>Solder Attach<br><br>1009850                   | 12-00557   | Hakko Hot Air<br>ReFlow Station                    | X   |  |     |  |     | --- | certification<br>assessment<br>1013136   | Requirement:<br>Distance<br><br><b>Verified</b><br>Requirements:<br>Visual Criteria<br>and Electrical             | as a result does not require an OQ/PQ to<br>be performed. However, PQ will be<br>performed to show repeatability in<br>meeting IPC Soldering Standards.<br><br>The output "Distance" is also 100%<br>verifiable; however the plan will be to<br>validate this output through PQ to<br>eliminate 100% verification in process. |
|   | 1008923  | MainBaseAssy                                       | X   |  |     |  |     | --- |  |   |   |
|   | 1008922  | SolderFixNest                                      | X   |  |     |  |     | --- |  |   |   |
|   | ---  | Tappi Chart  | --- |  |     |  |     | --- |  |   |   |
|   | 1011890  | Spacer Comb  | X   |  |     |  |     | --- |  |   |   |
| Graphite Sheet<br>and Battery<br>Insulator<br>Attachment<br><br>1010895 | 1012174  | FT Side<br>Graphite Sheet<br>Attach Fixture        | X   |  | --- |  |     | --- | NA   | <b>Verified</b><br>Requirements:<br>Visual Criteria<br>and<br>Dimensional   | Output is and will be 100% verified and<br>as a result does not require an OQ/PQ to<br>be performed.  |
| Battery Attach<br><br>1010551   | 12-00396   | ILT 1500 Fiber<br>Laser                            | X   |  |     |  |     | X   | Training<br>certification<br>assessment<br>1013136<br><br>TMV<br><br>Calibration | Validated<br>Requirement:<br>Tensile<br><br><b>Verified</b><br>Requirements:<br>Visual Criteria<br>and Electrical | Validated output is not 100% verifiable.<br>OQ and PQ will be performed to ensure<br>we can meet our validated output<br>requirement at challenge process<br>parameters as well as across multiple<br>setups/material lots where applicable.<br>Tensile strength will be our validated<br>output.                             |
|   | 1011594  | Battery Flag<br>Bending<br>Fixture                 | X   |  | X   |  | X   | --- |  |   |   |
|   | 1011593  | Battery<br>Welding<br>Fixture                      | X   |  | X   |  | X   | --- |  |   |   |
|   | 12-00138   | Chatillon<br>Tensile Tester                        | X   |  | --- |  | --- | --- |  |   |   |
|   | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231 | Ophir Power<br>Meter and SH<br>to USB<br>Interface | --- |  | --- |  | --- | --- |  |   |   |



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|----------------------|--|---|-----|---------------------------|-----|-------------|---|---|-----|---|--|--|
|                      |  |   |     |                           |     |             |   | greater than or equal to 2.0<br>Reference 1013188 |     |   |  |  |
| Tack Weld<br>1010553 | 12-00395   | ILT 1500 Fiber Laser                      | X   | X                         | --- |             | X | Training certification assessment 1013136         | Low | Verified Requirements:<br>Visual Criteria | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. However, OQ will be performed to define production process windows for variable inputs. |  |
|                      | 1011639  | Tack Welding Fixture                      | X   |                           |     | ---         |   |   |     |   |  |  |
|                      | 13-00243   | Desiccant Drying Oven                     | X   | See Device Bake for OQ/PQ |     | ---         |   |   |     |   |  |  |
|                      | 11-00265<br>12-00401<br>12-00402<br>12-00728<br>13-00231<br>13-00232<br>13-00233<br>11-00266<br>12-00403<br>12-00404<br>13-00196 | Ophir Power Meter and SH to USB Interface | --- | ---                       | --- | Calibration |   |   |     |   |  |  |
|                      |  |   |     |                           |     |             |   |   |     |   |  |  |
|                      |  |   |     |                           |     |             |   |   |     |   |  |  |

|                                 |          |   |   |   |   |   |   |     |   |  |
|---------------------------------|----------|---|---|---|---|---|---|-----|---|--|
| Seam Weld Bake Cycle<br>1010495 | 12-00095 | ILT Glovebox Antichamber                  | X | X | X | X | Training certification assessment 1013136 | Low | Validated Requirement: Internal Moisture  | Validated output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement at challenge process parameters as well as across multiple setups/material lots where applicable. Moisture content will be our validated output. |
|                                 | 12-00147 | ILT Glovebox Laser                        | X |   |   | X | Training certification assessment 1013136 |     | Validated Requirement: Weld penetration<br><br>Verified Requirements: Visual Criteria and Hermeticity | Validated output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement at challenge process parameters as well as across multiple setups/material lots where applicable. Weld penetration will be our validated output. |
|                                 | 1010364  | Seam Welding Fixture                      | X | X | X |   |   |     |   |  |
|                                 | 11-00265 | Ophir Power Meter and SH to USB Interface |   |   |   |   |   |     |   |  |
|                                 | 12-00401 |   |   |   |   |   |   |     |   |  |
|                                 | 12-00402 |   |   |   |   |   |   |     |   |  |
|                                 | 12-00728 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00231 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00232 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00233 |   |   |   |   |   |   |     |   |  |
|                                 | 11-00266 |   |   |   |   |   |   |     |   |  |
| Seam Weld<br>1010554            | 12-00403 |   |   |   |   |   |   |     |   |  |
|                                 | 12-00404 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00196 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00234 |   |   |   |   |   |   |     |   |  |
|                                 | 13-00235 |   |   |   |   |   |   |     |   |  |
| Hermetic Leak Test              | NA       | Cross Section Equip                       | X |   |   |   | NA  | Low | Verified Requirements: Leak Rate,   | Output is 100% verifiable. Test Method Validation for leak rate and thickness  |
|                                 | 12-00436 | Leak Tester                               | X |   |   |   |   |     |   |  |
|                                 | 13-00218 | Testing Fixture                           | X |   |   |   |   |     |   |  |



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|---------------------------------------|--------------------|------------------------------------|-----|-----|-----|-----|-----|-----|-----|---|------------|---|--|
| 1010778                               |                    | -- Drop in fixture                 |     |     |     |     |     |     |     | Dimensional                               |            |   |  |
|                                       | 12-00503           | Calibrated Leak Tools              | --- | --- | --- | --- | --- | --- | --- |   |            |   |  |
| Surface Finishing/Blasting<br>1007659 | 12-00542           | Comco Blasting System              | X   | --- | --- | --- | --- | --- | --- | Verified Requirements:<br>Visual Criteria | Acceptable | Training certification assessment 1013136             | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed.   |
|                                       | 12-00543           | AER Dust Collector                 | X   | --- | --- | --- | --- | --- | --- |   |            |   |  |
|                                       | 12-00533           | MKS 6115 DI Air Gun                | X   | --- | --- | --- | --- | --- | --- |   |            |   |  |
|                                       |                    |                                    |     |     |     |     |     |     |     |   |            |   |  |
| Laser Marking<br>1010786              | 12-00079           | Keyence                            | X   | X   | --- | --- | --- | X   | --- | Verified Requirements:<br>Visual Criteria | Acceptable | Training certification assessment 1013136 Calibration | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. However, OQ will be performed to define production process windows for variable inputs. |
|                                       | 1010787 / 1010788  | Marking Fixture                    | X   | --- | --- | --- | --- | --- | --- |   |            |   |  |
|                                       | 11-00265           | Ophir Power Meter and Nova Display | --- | --- | --- | --- | --- | --- | --- |   |            |   |  |
|                                       | 12-00401           |                                    |     |     |     |     |     |     |     |   |            |   |  |
|                                       | 12-00402           |                                    |     |     |     |     |     |     |     |   |            |   |  |
|                                       | 12-00728           |                                    |     |     |     |     |     |     |     |   |            |   |  |
|                                       | 13-00231           |                                    |     |     |     |     |     |     |     |   |            |   |  |
|                                       | 13-00232           |                                    |     |     |     |     |     |     |     |   |            |   |  |
| 13-00233                              |                    |                                    |     |     |     |     |     |     |     |   |            |   |  |
| 13-00230                              |                    |                                    |     |     |     |     |     |     |     |   |            |   |  |
| Header to IPG Pin Press<br>1005238    | 12-00266/ 67/68/69 | Pin Press Fixturing                | X   | --- | --- | --- | --- | --- | --- | Verified Requirements:<br>Visual Criteria | Low        | Training certification assessment 1013136             | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed.   |
|                                       | NA                 | Arbor press                        | X   | --- | --- | --- | --- | --- | --- |   |            |   |  |
| Lead Frame Welding                    | 11-00246           | ILT 1500 NdYag Laser               | X   | X   | X   | X   | X   | X   | X   | Validated Requirement:<br>Tensile         | Low        | Training certification assessment                     | Output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement  |
|                                       | 1011591            | LF Welding                         | X   |     |     |     |     |     |     |   |            |   |  |



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| 1005413/1005414    | (3x8)<br>1012548 | Fixtures                    |   |   |  | 1013136   | Verified<br>Requirements:<br>Visual Criteria | at challenge process parameters as well as across multiple setups/material lots were applicable.<br>Tensile strength will be our validated output. |
|                    | (2x12)           |                             |   |   |  |   |  |  |
|                    | 11-00265         |                             |   |   |  | Training certification assessment 1013136   |  |  |
|                    | 12-00401         |                             |   |   |  |   |  |  |
|                    | 12-00402         |                             |   |   |  |   |  |  |
|                    | 12-00728         |                             |   |   |  |   |  |  |
|                    | 13-00231         |                             |   |   |  |   |  |  |
|                    | 13-00232         |                             |   |   |  |   |  |  |
|                    | 13-00233         |                             |   |   |  |   |  |  |
|                    | 11-00266         |                             |   |   |  |   |  |  |
|                    | 12-00403         |                             |   |   |  |   |  |  |
|                    | 12-00404         |                             |   |   |  |   |  |  |
|                    | 13-00196         |                             |   |   |  |   |  |  |
|                    | 13-00234         |                             |   |   |  |   |  |  |
|                    | 13-00235         |                             |   |   |  |   |  |  |
|                    | 12-00138         | Chatillon<br>Tensile Tester | X |   |  | Not Required:<br>Capability index greater than or equal to 2.0<br><br>Reference 1013039 |  |  |
| Header/IPG Bonding | 13-00219         |                             | X |   |  |   | Validated<br>Requirement:<br>13 lb           | Output is not 100% verifiable. OQ and PQ will be performed to ensure we can  |
|                    | 12-00388         | EFD Dispenser               |   | X |  |   |  |  |
|                    | 11-00390         | Cure Oven                   | X |   |  | Training certification assessment   |  |  |



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| 1008609   | 12-00138             | Chatillon<br>Tensile Tester   | X | --- | --- | --- | 1013136  | minimum<br>tensile when<br>tested per<br>header bond<br>test method<br>on either side. | meet our validated output requirement<br>at challenge process parameters as well<br>as across multiple setups/material lots<br>were applicable.<br>Tensile strength will be our validated<br>output. |
|   |                      |                               |   |     |     |     | TMV  | Verified<br>Requirements:<br>Visual Criteria   |  |
| Header Fill<br>1006560  | 12-00388<br>13-00219 | EFD Dispenser                 | X | --- | --- | --- | Training<br>certification<br>assessment<br>1013136 | Verified<br>Requirements:<br>Visual Criteria   | Output is and will be 100% verified and<br>as a result does not require an OQ/PQ to<br>be performed.   |
|   | 12-00391 /<br>93     | Vacuum<br>Chamber and<br>Pump | X | --- | --- | --- |  |  |  |
|   | 09-00400             | Autoclave                     | X | --- | --- | --- |  |  |  |
| Final Inspection /<br>Borescope<br>Inspection<br>1007803 /<br>1007700 | 12-00413             | Bore<br>Inspection            | X | --- | --- | --- | Training<br>certification<br>assessment<br>1013136 | Verified<br>Requirements:<br>Visual Criteria<br>And<br>Dimensional                     | Output is and will be 100% verified and<br>as a result does not require an OQ/PQ to<br>be performed.   |
|   |                      |                               |   |     |     |     |  |  |  |
|   | 1009901              | Nest Fixturing                | X | --- | --- | --- |  |  |  |
| IPG Final<br>Electrical<br>Inspection<br>1011107                      | X                    | Electrical Test<br>5          | X | X   | X   | X   | TMV  | Verified<br>Requirements:<br>Electrical  | 100% electrical verification/inspection  |
|   | X                    | Test Fixture                  | X |     |     | --- |  |  |  |
| IPG Charging  | X                    | Charging<br>Equipment         | X | X   | X   | X   | TMV  | Verified<br>Requirements:  | 100% electrical verification/inspection of<br>charge level   |



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|---------------------------------|---|----------------------------|-----|-----|-----|-----|---|------------|--------------------------------------|--|
| 1013904                         | X   | Test Fixture               | X   |     |     | --- |   |            | Electrical                           |  |
| Label Generation                | Reference 1013324 Master Process Validation Plan, Label Generation          |                            |     |     |     |     |   |            |                                      |  |
| 1013815                         |   |                            |     |     |     |     |   |            |                                      |  |
| Accessory Pouch Sealing 1007849 | 13-00164  | Van der Stahl Pouch Sealer | X   | --- | --- | --- | ---                                       | Acceptable | Verified Requirements: Visual        | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed. This is not a sterile barrier.  |
| Sterile Packaging 1007791       | E0315   | Belco Sealer               | X   |     |     | --- |   | Low        | Validated Requirement: Peel Strength | Output is not 100% verifiable. OQ and PQ will be performed to ensure we can meet our validated output requirement at challenge process parameters as well as across multiple setups/material lots were applicable. |
|                                 | 11-00363  | Tray Nest                  | X   | X   | X   | --- | TMV                                       |            | Verified Requirements: Visual        | Tensile strength will be our validated output.   |
| Sterilization/Qualitative       | Reference QAQP 0093 Algostim EtO Sterilization Strategy and Validation Plan |                            |     |     |     |     |   |            |                                      |  |
| 1013816                         |   |                            |     |     |     |     |   |            |                                      |  |
| Label Generation                | Reference 1013324 Master Process Validation Plan, Label Generation          |                            |     |     |     |     |   |            |                                      |  |
| 1013815                         |   |                            |     |     |     |     |   |            |                                      |  |
| Final Pack 1007792              | ---   | ---                        | --- | --- | --- | --- | Training certification assessment 1013136 | Low        | Verified Requirements: Visual        | Output is and will be 100% verified and as a result does not require an OQ/PQ to be performed.   |