

# FIRST ARTICLE REPORT

## Section I: Material Identification and Classification

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Description: \_\_\_\_\_

Supplier Name: \_\_\_\_\_ Vendor #: \_\_\_\_\_

Material Classification (circle one):	Critical to User/Patient Safety	High Complexity	Moderate Complexity	Off-the-Shelf / Low Complexity
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Supplier Certification (circle one):	Certified	Uncertified
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Supplier Capability (circle one):	Producing Higher / Similar Complexity Material	Producing Less Complex Material
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Resulting Risk Level (see 06ti109):	I	II	III
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Risk Level Approval	Print Name	Sign Name	Date
Quality Assurance			
R&D / Product Engineering			

## Section II: Non-Electronic FAR Requirements Determination

Indicate additional requirements by checking the appropriate block. Minimum requirements are already indicated.

	Risk Level: III		Risk Level: II		Risk Level: I	
	Supplier	Stryker	Supplier	Stryker	Supplier	Stryker
	FAR Requirement					
1. Receiving inspection per attribute chart.	N/A	■	N/A	■	N/A	■
2. Supplier certification that material meets all requirements*	<input type="checkbox"/>	N/A	■	N/A	■	N/A
3. Single piece inspected for all Required Characteristics**	<input type="checkbox"/>	<input type="checkbox"/>	■	<input type="checkbox"/>	■	■

\*If required, "Supplier Certification" should be listed in the Required Characteristics Determination section.

\*\*Section IV, Required Characteristics Determination, must be filled out and sent to supplier.

**Note:** See Section III, Electronic Assembly Requirements, for determining the requirements for electronic assemblies.

# FIRST ARTICLE REPORT

## Section III: Electronic Assembly Requirements

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Supplier: \_\_\_\_\_

Solder Class (circle one):      Class 1              Class 2              Class 3              N/A

Flux Type (circle one):              Clean              No Clean              N/A

## Supplier Requirements – Printed Circuit Boards

**Note:** Indicate additional requirements by checking the appropriate block. Minimum requirements are already indicated.

**Note:** A copy of this page and Section IV (if any Required Characteristics are necessary) shall be given to the supplier.

Risk Level (circle one):		Requirement
I	II or III	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1. Provide Bill of Material
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2. Provide software checksum (equipment used and value)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Provide process control plan
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4. Provide certification of testing
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Provide printed copies of test data
<input type="checkbox"/>	<input type="checkbox"/>	6. Inspect for Required Characteristics listed in Section IV

## Supplier Requirements – Cables

**Note:** Indicate additional requirements by checking the appropriate block. Minimum requirements are already indicated.

**Note:** A copy of this page and Section IV (if any Required Characteristics are necessary) shall be given to the supplier.

Risk Level (circle one):		Requirement
I	II or III	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1. Provide Bill of Material
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2. Provide certification of testing and test method
<input type="checkbox"/>	<input type="checkbox"/>	3. Inspect for Required Characteristics listed in Section IV

Supplier Inspector: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Sign
Print Name
Date

## FIRST ARTICLE REPORT

### Section III: Electronic Assembly Requirements (Continued)

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Supplier: \_\_\_\_\_

#### Stryker Requirements – Printed Circuit Boards and Cables

**Note:** Indicate additional requirements by checking the appropriate block. Minimum requirements are already indicated.

Risk Level (circle one):		Requirement
I	II or III	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1. Review all required information from supplier*
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Review and approve bare board used*
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3. Ensure packaging meets ESD requirements per 09ti601*
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Test material in final product*
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	5. Inspect material per the attribute chart
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Visually inspect material for solder class and cleanliness
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Re-inspect product per Section IV, Required Characteristics (if applicable)

**\*Must be performed by the responsible Manufacturing, Product, or R&D Engineer**

**Comments / Discrepancies:**

# FIRST ARTICLE REPORT

## Section IV: Required Characteristics Determination

**Note:** If not required by Section II or Section III, this section need not be included in the FAR packet.

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Supplier: \_\_\_\_\_

**Directions for Supplier:**

1. Inspect material for all characteristics listed in the table.
2. Record measurement or test results and gage used in the table, or submit data showing measurement / test results.
3. Clearly segregate the piece inspected from the remainder of the material being submitted.

**Directions for Stryker Incoming Inspection:**

1. Refer to Section II or Section III of the form to determine if verification of supplier results is required. If required, perform the inspection / test operations listed in the table on the segregated piece and record results.

Char. #	Specification	Supplier Results		Stryker Results	
		Gage Used	Reading	Gage Used	Reading
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

**Note:** Use the Continuation Page if additional characteristics are required.

Supplier Inspector: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Sign
Print Name
Date

# FIRST ARTICLE REPORT

## Section IV: Required Characteristics Determination (Continuation Page)

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Supplier: \_\_\_\_\_

Char. #	Specification	Supplier Results		Stryker Results	
		Gage Used	Reading	Gage Used	Reading
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					

Supplier Inspector: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Sign Print Name Date

**Supplier Comments:**

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**Stryker Comments:**

# FIRST ARTICLE REPORT

## Section V: Approvals

Part #: \_\_\_\_\_ Rev Level: \_\_\_\_\_ Supplier: \_\_\_\_\_

The material has been inspected and conforms to all requirements listed in the previous sections.

The material is acceptable for unrestricted use in production.

The supplier has confirmed their ability to manufacture the listed material.

Title	Printed Name	Signed Name	Date
Quality Control			
Quality Engineer			
Product / R&D / Mfg. Eng.			

Notification of approval should be sent to the supplier.

The original FAR form, including all required sections and any supplier data, should be filed in the attribute chart.