



Non-conformance Form

990-03826-00

Rev 1

Revision History		
Rev	Description Of Change	Effective Date
1	Initial Release	6/14/2019

Initiator: Gabriella Levine	Date: 6/24/2019	NCR Log #: NA
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Nonconformance Identification	
Description of Nonconformance: According to G5269 690-14168-01 Partial FAI, the connector sticker fixture has multiple out of spec dimensions according to the engineering drawing. This inspection was a full FAI of the assembled part. Part Number: 690-14168-01 Description: Mech, Fixture, Label Alignment, Amber Serial Number: SF19062401	
Does Non-conformance Impact Product? <i>(check one)</i>	
YES ____ Conduct a Risk Analysis	NO __ X __ Determine if Systemic Issue



Risk Management File Reference	
Document Title: N/A	File location reference: N/A
DMR Reference: N/A	DHR Reference: N/A


Results of Risk Analysis
N/A

Non-conformance Disposition (check one)					
CAPA (non-products only)	Use As Is	Rework	Return to Supplier	Lab Use Only	Scrap
_____	<u> X </u>	_____	_____	_____	_____
Rationale: The tool still functions as intended, to align the label on the bioamp enclosure bottom. The tool is not a critical component to building the system. Tool was tested with many production enclosure parts and no fit issues were realized. Non-conformances are not expected to impact assembly nor finished product quality.					

Dispositioned by: Gabriella Levine	Date: 6/24/2019
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CAPA Determination	
N/A	
Is a CAPA Required? (check one)	
YES _____ New CAPA# Assigned: _____	NO <u> X </u>
Rationale: Part functions as intended and no further action is required.	

NCR Approval	
Print Name / Title:	Gabriella Levine
Signature:	
Date:	6/14/2019

REWORK Determination
Applicable? Yes _____ No _____ N/A <u> X </u>
Rework Protocol Title: N/A



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Protocol #: N/A		Revision: N/A	
Description: N/A			
Approver Name:	N/A		
Signature:	N/A		
Date:	N/A		
Rework Protocol			
Rework Work Instruction: N/A			
Predefined Acceptance Criteria:	N/A		
Results (Select one):	PASS		FAIL
Test report reference:	N/A		
Summary: N/A			
MRB Approver Name and Title:	N/A		
Approval Signature:	N/A		
Date:	N/A		

Remain in non-conforming state: Use As Is, Return to Supplier, Lab Use Only, Scrap
Additional Information for Product Disposition – Use As Is
Applicable? Yes <u> X </u> No <u> </u> N/A <u> </u>



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Rationale for Disposition: Use As Is		The tool still functions as intended, to align the label on the bioamp enclosure bottom. The tool is not a critical component to building the system. Tool was tested with many production enclosure parts and no fit issues were realized. Non-conformances are not expected to impact assembly nor finished product quality.
DMR / DHR Ref:	N/A	
Additional Information for Product Disposition – Return to Supplier		
Applicable? Yes _____ No _____ N/A <u> X </u>		
Return to Supplier Authorization Number, if applicable:		
Additional Information for Product Disposition – Lab Use Only		
Applicable? Yes _____ No _____ N/A <u> X </u>		
Rationale:		
Labeled “Lab Use Only”? (check one)	YES _____ NO _____	Material Location: N/A
Confirmed by Signature:	N/A	
Date:	N/A	
Additional Information for Product Disposition – Reject to Scrap		
Applicable? Yes _____ No _____ N/A <u> X </u>		
Proper Disposal? (check one)	YES _____ NO _____	Rationale: N/A



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MRB Approver Name and Title:	N/A
Approval Signature:	N/A
Date:	N/A