

Production Order: 500000296544



Production Order Document
Production Order Qty: 500
PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Material Type:	ZFRT	Description: Edwards Flex Shaft Commander 155885	Order Type: ZSTD
Production Version:	7988		Project Phase:
Plant / Business Unit:	1213 / AC5		

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials																								
50	KITTING3 Kitting Devices  Kitting Devices	<p>Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>KD2 8:30am 18 Jan 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 6:8 7:20 am 20 Jan 24</u> Record Dryer Shelf #: <u>N/A</u></p>	N/A	N/A	17 JAN 24	OLAC																								
		<table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>1000-2053-01</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000278880</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000288401</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	1000-2053-01	A <u>A</u>	PC	500	<u>0000278880</u>	<u>500</u>					<u>N/A</u>	<u>N/A</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>				
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																									
1000-2053-01	A <u>A</u>	PC	500	<u>0000278880</u>	<u>500</u>																									
				<u>N/A</u>	<u>N/A</u>																									
MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>																									

Notes: DA 2564, 2484

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	58497	N/A	200		
		TL0167-02	E	<u>E</u>	PC	70	N/A	N/A	Bulk		
		TL0165-05	J	<u>J</u>	PC	5	N/A	N/A	Bulk		
		TL0165-03	J	<u>J</u>	PC	5	N/A	N/A	Bulk	N/A	N/A
		141967-01	02	<u>02</u>	PC	500	85500	N/A	525		
		RM7349-02	C	<u>C</u>	PC	543	82854	N/A	327		
		RM7348-01	C	<u>C</u>	PC	500	78689 82881 82883	300 150 150	200		

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM4001-01	B	<u>B</u>	PC	125	<u>82468</u>	<u>200</u>			
		RM0607-01	D	<u>D</u>	PC	56	<u>78322</u>	<u>62</u>			
		RM0498-01	C	<u>C</u>	PC	500	<u>0000275491</u>	<u>500</u>			
		RM0362-01	E	<u>E</u>	PC	594	<u>80239</u>	<u>600</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>			
		MM1538-01	A	<u>A</u>	PC	500	<u>0000278970</u>	<u>500</u>			
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000284209</u>	<u>1000</u>			

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1536-01	B	<u>B</u>	PC	500	<u>0000281413</u>	<u>60</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000281412</u>	<u>500</u>	<u>N/A</u>	
		MM0179-01	D	<u>D</u>	PC	500	<u>0000282489</u>	<u>500</u>	<u>N/A</u>	
		MM0178-01	E	<u>E</u>	PC	500	<u>0000276172</u>	<u>500</u>	<u>N/A</u>	
		MM0177-01	C	<u>C</u>	PC	500	<u>0000276174</u>	<u>500</u>	<u>N/A</u>	
		MM0176-01	D	<u>D</u>	PC	500	<u>0000271050</u>	<u>40</u>	<u>N/A</u>	<u>N/A</u>
		MM0074-01	G	<u>G</u>	PC	500	<u>0000284208</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
100	CATASY01 Catheter Assembly 1 	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	21Jan24 CB58	
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	21Jan24	YK140 SN67
	Major and Minor Mandrel Assembly					
Notes:						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1 	Loading Braid Stock	500	0	21Jan24	SC10 MC17
	Loading Braid Stock					
	Confirmation Reqd(Milestone)					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	21Jan24	AJ65 PY67
Notes:						
N/A						
N/A						
N/A						

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N/A	Trim Braid Wire at Proximal End Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
300	CATASY01 Catheter Assembly 1  Insert Cut Hypo Tube Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	21Jan24	RL47 PL22
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	21Jan24	CXG3 BD64

Notes:

N/A

N/A

N/A

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Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Load Tubing Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
400	CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)	Reflow	500	0	21Jan24	CD19 AL67 SN67 WTF
450	CATASY01 Catheter	FEP Removal	500	0	21Jan24	AM47 CD19 YH40
Notes:						
N/A						
N/A						
N/A						

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	Assembly 1 N/A	N/A	N/A	N/A	N/A	N/A
	FEP Removal					
	Confirmation Reqd(Milestone)					
500	CATASY01 Catheter Assembly 1 In-process Inspection and Rework Confirmation Reqd(Milestone) N/A N/A	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 87655 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A N/A	492	OF-III EW-III SCR-1 N/A	21Jan24 ⑧	LS46 CB87 AR02 PT09 SXII VC09
	Notes:	N/A N/A N/A	N/A	N/A	N/A	N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01 Catheter Assembly 1 	Remove Heat Shrink & Mandrel Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	481	MAH-III DL-III 11	2 Jan 24	VA96 LH45 TRN MH10
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	481	0	2 Jan 24	MH10

Notes:

N/A

N/A

N/A

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N/A	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 Loading Heat Shrink Confirmation Reqd(Milestone)	Loading Heat Shrink	481	0	21Jan24	P709
700	CATASY01 Catheter Assembly 1 Tipping	Tipping Record Tipping Oven Information: TMI: 09364 Cal Due: 31May24 TMI: 20830 Cal Due: 31May24 TMI: 6386 Cal Due: 31May24 TMI: 0521 Cal Due: 31May24	481	0	21Jan24	ILB3
Notes:						
N/A						
N/A						
N/A						

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N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
750	CATASY01 Catheter Assembly 1 	Tip Inspection/ Flash Removal Material Consumed: Part #: RM4001-01 Batch #: 82468 Qty: N/A Part #: RM0607-61 Batch #: 78322 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	481	0	21Jan24	IIC83
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	476	ACD-IHT 5	21Jan24	BD64 KL45
Notes:						
N/A						
N/A						
N/A						

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N/A	Major Mandrel Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
850	CATASY01 Catheter Assembly 1  Cut to Length Confirmation Reqd(Milestone)	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. Pass 2. Pass 3. Pass 4. Pass 5. Pass	475	SKU-1 ①	21Jan24	KL45 AL42 TRN
900	QUALITY1 Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	N/A	N/A	KX57
Notes:						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: 0700-01 Cal Due: 31MAY2024 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: 1000-1153-01 Batch #: 87655 Qty: N/A Part #: RM4001-01 Batch #: 82468 Qty: N/A Part #: RM0607-01 Batch #: 78322 Qty: N/A Part #: RM0158-01 Batch #: 58497 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A</p>	439	DEL-IH(SP) FM-11(ET) DL-IH(ET) SKV-HL(ET)① SCR-III(ET) EW-IH(I) DIS-IH(I) BP-1 36	21Jan24	DL07 LS46
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: N/A Cal Due: N/A Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Quality Inspection & Review  Confirmation Reqd(Milestone)	TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30 Sep 2025</u> TMI: <u>0692</u> Cal Due: <u>30 Sep 2025</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	434	DIS-1 STR-1 #505111 <u>5</u>	21Jan24	R14
1000	QUALITY1  Quality Inspection & Review  Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31 MAY 2024</u> Record Length Gage Information: TMI: <u>08890</u> Cal Due: <u>30 Sep 2024</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 Sep 2024</u>	430	LT-11 #3US_11 <u>4</u>	21Jan24	CBX

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review Quality Inspection & Review Confirmation Reqd(Milestone)	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	392	SCR-UH111 UH11 EW-UH11 ND-11 EH-11 FL-11 Del-11 KNK-1 BP-1 RDG-1 CRK-1 AB-1 	22Jan24	k155
1100	CATASY01 Catheter Assembly 1 Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): KPO2 22Jan24	N/A	N/A	22Jan24	KPO2

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
1150	PACKINT1 Packing assembly  Package Package, Label, and Ship Finished Parts Confirmation Reqd(Milestone)		392	0	23 Jan 24 AF10	

Notes:

N/A AF10 23 Jan 24 /

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Batch Number: 0000296544

By: AP10

Date: 23 Jan 24

Reviewed By:

RB29

Date:

23 JAH 24

Notes:

N/A AP10 23 Jan 24

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PN 12M0495-01

IN 77872

Compounding Solutions, LLC
258 Goddard Road
Lewiston, Maine 04240
Telephone: 207-777-1122 Fax: 207-777-1566

REV _____

Certificate of Analysis / Conformance

Customer: Creganna Medical
CS Part No.: RM0495-01
Description: Vestamid Care ML21, 20% Barium Sulfate, Blue PMS 289C

Lot Number: 2023-1979 Revision: E
Quantity Produced: 3654 lbs. Customer PO: 2620056888 Date of Mfg.: 17-Jul-2023

ASTM / TEST ID	TEST DESCRIPTION	TARGET	RANGE	RESULTS
QCP-001	Visual Inspection	PASS	PASS / FAIL	PASS
QCP-009	Color Analysis	Blue PMS 289C	PASS / FAIL	PASS
QCP-011	Pellet Size - Measurement Taken with Calipers	PASS	PASS / FAIL	PASS
ASTM D 1238	Melt Index - 230C / 2.16kg	-	-	2.6 g/10min
ASTM D 2240	Hardness - Shore D	-	-	75 D
ASTM D5630	Ash Content - Procedure B	22.50%	± 2.5%	22.5032%

Component Description	Lot Number	CAS Number	Batch Percent
Vestamid Care ML21	300380	25038-74-8	75.9061%
Blanc-Fixe XR-HN BaSO4	Y2126RA059	7727-43-7	22.50% ± 2.5%
Sunfast Blue L48-3747	C1QL0073	147-14-8	1.2600%
Sunfast Green L64-3107	CIOK01A1	1328-53-6	0.3122%
MPC Channel Black 3000132809 (Old 3000067230)	2022316089	1333-86-4	0.0187%

This document is to certify the above material supplied meets all customer requirements, including material characteristics and acceptance criteria, as stated in specifications, purchase orders and applicable agreements.

Refer to Compounding Solutions' QMF 116 for additional material information.

Taylor Kibbee 25JUL23

Taylor Kibbee, Quality Control Technician

Date



Compounding Solutions, LLC

258 Goddard Road

Lewiston, Maine 04240

Telephone: 207-777-1122 Fax: 207-777-1566

PN RM0425-01
UN 19157

Certificate of Analysis / Conformance

REV E

Creganna Medical

RM0495-01

Customer: Creganna Medical
CS Part No.: RM0495-01
Description: Vestamid Care ML21, 20% Barium Sulfate, Blue PMS 289C

Lot Number:	Customer Part No.:	Revision:
2023-2798	RM0495-01	E
3656 lbs.	Customer PO:	Date of Mfg.:
	2620059253	22-Aug-2023

ASTM / TEST ID	TEST DESCRIPTION	TARGET	RANGE	RESULTS
QCP-001	Visual Inspection	PASS	PASS / FAIL	PASS
QCP-009	Color Analysis	PASS	PASS / FAIL	PASS
QCP-011	Pellet Size - Measurement Taken with Calipers	Blue PMS 289C	PASS / FAIL	PASS
ASTM D 1238	Melt Index - 230C / 2.16kg	PASS	PASS / FAIL	PASS
ASTM D 2240	Hardness - Shore D	-	-	4.1 g/10min
ASTM D 5630	Ash Content - Procedure B	22.50%	± 2.5%	75 D 23.4834%

Component Description	Lot Number	CAS Number	Batch Percent
Vestamid Care ML21	300391	25038-74-8	75.9861%
Blanc-Fixie XR-HN BaSO4	Y2126RA059	7727-43-7	22.50% ± 2.5%
Sunfast Blue L48-3747	C1QL00D2	145-14-8	1.2600%
Sunfast Green L64-3107	C1QK01A1	1328-53-6	0.3152%
MPC Channel Black 3000132809 (Old 3000067230)	2022316089	1333-86-4	0.0187%

This document is to certify the above material supplied meets all customer requirements, including material characteristics and acceptance criteria, as stated in specifications, purchase orders and applicable agreements.

Refer to Compounding Solutions' QMF 116 for additional material information.

Taylor Kitbee 24 Aug 23

Taylor Kitbee, Quality Control Technician

Date



Compounding Solutions, LLC
258 Goddard Road
Lewiston, Maine 04240
Telephone: 207-777-1122 Fax: 207-777-1566

Certificate of Analysis / Conformance

Customer: Greganna Medical
CS Part No.: RM0495-01
Description: Vestamid Care ML21, 20% Barium Sulfate, Blue PMS 289C

Lot Number: 2023-0749 Revision: E
Quantity Produced: 3654 lbs. Customer Part No.: RM0495-01
Customer PO: 2620053853 Date of Mfg.: 13-Mar-2023

ASTM / TEST ID	TEST DESCRIPTION	TARGET	RANGE	RESULTS
QCP-001	Visual Inspection	PASS	PASS / FAIL	PASS
QCP-009	Color Analysis	Blue PMS 289C	PASS / FAIL	PASS
QCP-011	Pellet Size - Measurement Taken with Calipers	Blue PMS 289C	PASS / FAIL	PASS
ASTM D 1238	Melt Index - 230C / 2.16kg	-	-	3.8 g/10min
ASTM D 2240	Hardness - Shore D	-	-	76 D
ASTM D5630	Ash Content - Procedure B	22.50%	± 2.5%	22.4779%

Component Description	Lot Number	CAS Number	Batch Percent
Vestamid Care ML21	300342	25038-74-8	75.9061%
Blanc-Fixe XR-HN BaSO4	Y2D11RA029	7727-43-7	22.50% ± 2.5%
Sunfast Blue L48-3747	C1QL0073	147-14-8	1.2600%
Sunfast Green L64-3107	C1QB0030	1328-53-6	0.3152%
MPC Channel Black 3000132809 (Old 3000067230)	2022260776	1333-86-4	0.0187%

This document is to certify the above material supplied meets all customer requirements, including material characteristics and acceptance criteria, as stated in specifications, purchase orders and applicable agreements.
Refer to Compounding Solutions' QMF 116 for additional material information.

Taylor Kibbee 17Mar23
Taylor Kibbee, Quality Control Technician Date

P/N RM0495-01

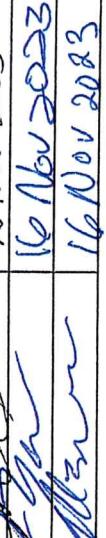
LN CG272

Entered to Hansa 3228 1/1/2023
Entered to 13 Feb 2024 3228 V/A/2024

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: DA2564

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DEVIATION AUTHORIZATION FORM

Requestor Name:	Krishna Selvaraj		
Document Number Affected	Revision		
Doc #3005206 (MPI0238)	BP		
Deviation From:	Deviation To:		
Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer, check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.	Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer at OPER900 (TMI0700-01) , check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.		
Justification: TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable. TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.			
Part Number Affected	Revision		
SA0155-01	H		
Start Date:	End Date:	Lot Number:	
16 Nov 23	15 DEC 23	N/A	
Risk Assessment: Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A			
If yes to any of the above, what controls are being put in place to mitigate the risk – N/A			
Corrective Action Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.			
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: N/A			
Title	Approval Name	Approval Signature	Date
Engineering Manager	Jake Stanislowski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

Bridges at Socorro 11/15/23



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158

Expend to 22 May 2023 DEVIATION A
Below to 20 Dec 2023

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NOTIFICATION FORM Extended to 23 Oct 2023
See attached email extension to 24 SEP 23
1512
24 AUG 23 J28
24 SEP 23 J28

Requestor Name: Udhesh Kapadnis

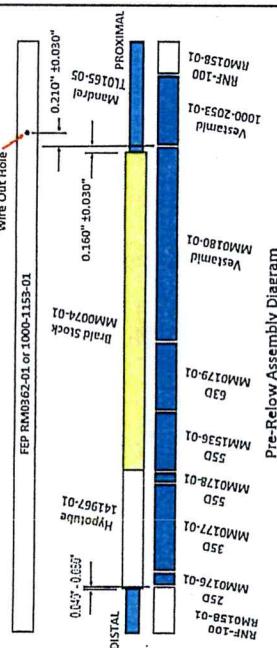
Document Number Affected	Revision
3107610	L

Deviation From:

QIP3107610, Section 8.0 Inspection Requirements
(Supplemental Visual Inspection) OP 1050:
Current QIP3107610 does not state to inspect for the
correct extrusion configuration.

correct extrusion configuration.

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Deviation To:

This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050.

See instructions attached to this DA.

A.

Justification: Recently it has been found that operators are incorrectly assembling MM0179-01 and MM1536-01. The event documents in NC-26390, and NC-26426. Only few of experienced inspectors can detect finished unit that contains incorrect extrusion configuration, and inexperienced inspectors may not which potential non-conformance unit sent to customer. Interim correction action has been implemented at OP 250, 300, 350 to detect unit built with out of oriented extrusions. This DA is adding another layer of inspection at final QC inspection to avoid incorrect assembly defects.

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	N/A

Digitized by srujanika@gmail.com

Kiss Assessment: Is there any statistical significance?

Is there any potential
Control Plans

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Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If no, explain:	No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects.
Training Required:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no explain:

① UK55, 23 JwJ 2023

2484
2468
①

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Description/Objectives of Training:
DA- Inspection at final QC, Op#1050.

Group Training Record

Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and ~~MM1536-02~~ fixture for inspection. (See image 1)
① MM0179-01 *Type Correction TS12*
10AUG-23



Image- 1

Step 1:

- Visually locate the MM0180-01 (Vestamid) transition to MM0179-01 on the completed part approximately 9.75" from the distal end using magnification light 2.25X minimum.
- Align the fixture MM0179-01 extrusion proximal end to the Vestamid transition on completed part.
(See image 2)



Image- 2

- Visually verify the MM0179-01 distal end of the fixture is approximately at the same location on the completed part. (See image 3)

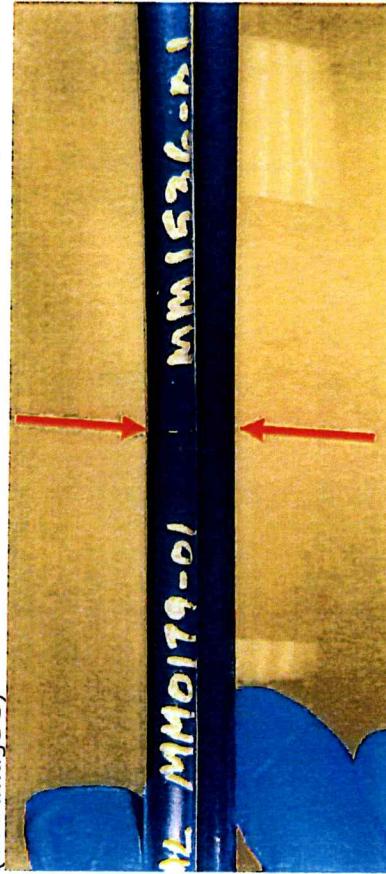


Image- 3

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, move to Step 2.

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Step 2:

- Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)

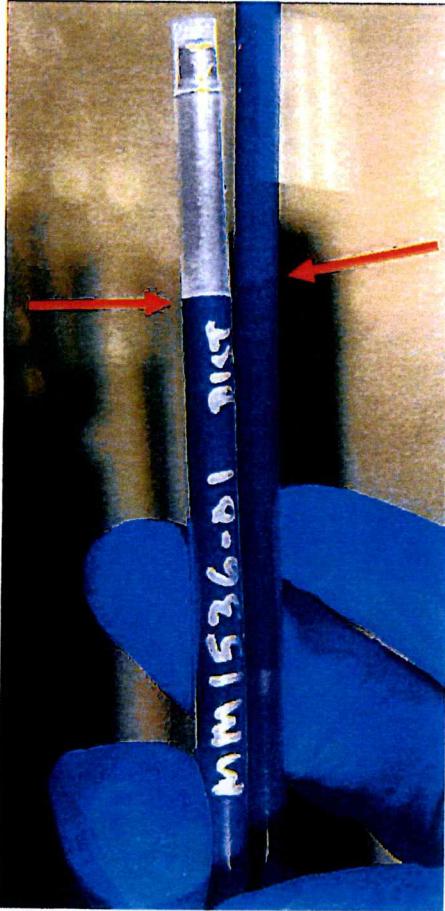


Image- 4

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, the part passes inspection.
- Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

1	MM0179-01	MM1536-01
GOOD PART		
2	MM1536-01	MM0179-01
MM0179-01 and MM1536-01 Wrong Order - BAD PART		
3	MM0179-01	MM0179-01
Two MM0179-01 - BAD PART		
4	MM1536-01	MM1536-01
Two MM1536-01 - BAD PART		

Image - 5

Title	Approval Name	Approval Signature	Date
Mgr. Quality Engineering	Hai Nguyen		25 Jul 2023
Mgr. Manufacturing Engineering	Jake Stanislawski		25 Jul 2023
Mgr. Operations	Matthew Benson		25 Jul 2023

FIM0002.RevF

Deviation Authorization

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Document No: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000294544

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	8:05 AM	430	AL67	20Jan24	8:17 am	415	AL67	20Jan24	16
TM10745	44	8:29 am	430	cm99	20Jan24	8:41am 8:31am①	415	cm99	20Jan24	16
TM10745	44	9:43am	430	cm99	20Jan24	9:55am	415	cm99	20Jan24	16
TM10745	44	11:04 AM	430	AL67	20Jan24	11:16AM	415	AL67	20 Jan 24	16
TM10745	44	11:40AM	430	PL22	20Jan24	11:52AM	415	PL22	20 Jan 24	16
TM10745	44	12:20 PM	430	CD19	20Jan24	12:32PM	415	CD19	20 Jan 24	16
TM10745	44	1:25pm	430	SN67	20Jan24	1:37pm	415	SN67	20 Jan 24	16
TM10745	44	1:52pm	430 - SN67		20Jan24	2:04pm	415	SN67	20 Jan 24	16
TM10745	44	2:10pm	430	cm99	20Jan24	2:22pm	415	cm99	20 Jan 24	16
TM10745	44	2:35 PM	430	RL47	20Jan24	2:47pm	415	RL47	20 Jan 24	16
TM10745	44	3:20pm	430	cm99	20Jan24	3:32pm	415	cm99	20 Jan 24	15
TM10745	44	4:35pm	430	cm99	20Jan24	4:47pm	415	cm99	20 Jan 24	16

① cm99 20Jan24



Document No: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000296544

OP 400

① cm99 20 Jan 24



Document No: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000296544

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	7:50AM	430	CD19 ①②	20Jan24	8:02AM ①②	415	CD19	20Jan24	16
TM10942	44	8:15AM	430	KL4S	20JAN24	8:27AM	415	KL4S	20JAN24	16
TM10942	44	9:16AM	430	AL67	20 Jan 24	9:28AM	415	AL67	20 Jan 24	16
Tm10942	44	9:31am	430	cm99	20Jan24	9:43am	415	cm99	20Jan24	16
TM10942	44	9:57AM	430	RV16	20Jan24	10:07AM	415	RV16	20Jan24	16
Tm10942	44	10:15AM	430	CD19	20Jan24	10:27AM	415	CD19	20Jan24	16
TM10942	44	10:29AM	430	RV16	20 Jan 24	10:41 AM ③④	415	RV16	20 Jan 24	16
TM10942	44	10:49AM	430	AL67	20 Jan 24	11:01AM	415	AL67	20 Jan 24	16
Tm10942	44	11:17AM	430	CD19	① 20Jan24 ② 11:29AM	11:29AM	415	CD19	20Jan24	16
Tm10942	44	11:55AM	430	CD19	20 Jan 24	12:07pm	415	CD19	20 Jan 24	16
Tm10942	44	1:18PM	430	SN67	20Jan24	1:30pm	415	SN67	20 Jan 24	16
Tm10942	44	1:43PM	430	SN67	20Jan24	1:55pm	415	SN67	20 Jan 24	16

① RV16 20Jan24
② CD19 20Jan24
② CB58 20Jan24



Document No: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000296544

OP 400

PRODUCTION ORDER# 500000296544

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	11:04 AM	190F	KL4S	20JAN24	12:14 PM	190F	KL4S	20JAN24	40
TM10409	N/A	12:08 PM	190F	AL42	20JAN24	01:18PM	190F	AL42	20JAN24	40
TM10409	N/A	1:25PM	190F	BD64	20JAN24	2:35PM	190F	BD64	20JAN24	30
TM12036 TM10409	N/A	2:00PM	190F	BD64	20Jan24	3:10PM	190F	BD64	20Jan24	40
TM10409	N/A	3:10PM	190F	BD64	20Jan24	4:20PM	190F	BD64	20Jan24	41
TM10409	N/A	5:00PM	190F	BD64	20Jan24	6:10PM	190F	BD64	20Jan24	47
TM10409	N/A	4:45AM	190F	AL42	21JAN24	5:55AM	190F	AL42	21JAN24	29
TM12036	N/A	6:55AM	190F	AL42	21JAN24	8:05AM	190F	AL42	21JAN24	48
TM10409	N/A	7:20 AM	190F	KL4S	21JAN24	8:30 AM	190F	KL4S	21JAN24	25
TM12036	N/A	8:09 AM	190F	KL4S	21JAN24	9:19 AM	190F	KL4S	21JAN24	35
TM10409	N/A	8:33 AM	190F	KL4S	21JAN24	9:43 AM	190F	KL4S	21JAN24	21
TM12036	N/A	9:39 AM	190F	KL4S	21JAN24	10:49 AM	190F	KL4S	21JAN24	37
TM10409	N/A	10:30 AM	190F	KL4S	21JAN24	11:40 AM	190F	KL4S	21JAN24	43

① BD64 20Jan24



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000296544

OP #: 500 Shift #: 3rd

Total Parts Reworked:		34	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		10
EW	Exposed Wire	HHH	22
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks	N/A	N/A
VD	Voids	HH	12
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

SXII, VC09, AR02 19 Jan 24 ① 20 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check): ① CB58 20 Jan 24



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000796544 OP #: 500 Shift #: 3

Total Parts Reworked:		<u>30</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>N/A</u>	<u>N/A</u>
EH	Exposed Hypotube	<u>III II</u>	<u>7</u>
EW	Exposed Wire	<u>III III III III III III</u>	<u>30</u>
MP	Micropores	<u>N/A</u>	<u>N/A</u>
SCR	Scratch	<u>III</u>	<u>5</u>
SKV	Skive Marks	<u>II</u>	<u>2</u>
VD	Voids	<u>N/A</u>	<u>N/A</u>
<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
Inspected By (Sign and Date):		<u>PT09 20 Jan 24</u>	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 5106073

Rev: E

Document Type: Manufacturing Form

Title: SA0155-01 Visual Rework Form

PO #: 500000296544 **OP #:** 500 **Shift #:** 3

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):

- CONFIDENTIAL -

Page 1 of 1

Status CURRENT Effective 5/8/2023



Document No: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 500 000 296 544 OP #: 750 Shift #: 3

Total Parts Reworked:		42	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		10
DIM07 US / WC	DIM07 Undersized (Window Closed)		7
EH	Exposed Hypotube		20
GD	Glue Damage		5
Inspected By (Sign and Date):		ILB3 21 JAN 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000296544OP #: 900 Shift #: 3245

Total Parts Reworked:			
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u> </u>	13
EH	Exposed Hypotube	<u> </u>	10
EW	Exposed Wire	<u> </u>	89
MP	Micropores	<u> </u>	12
SCR	Scratch	<u> </u>	142
SKV	Skive Marks	<u> </u>	6
VD	Voids	<u> </u>	41
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	<u> </u>	16
DIM06 OS	DIM06 OD Oversized	<u> </u>	12
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		<u>D207, LS46, KX54</u>	<u>21 Jan 24</u>

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

Maximum Force Reached During Tensile Test (10 samples accepted from final inspection for each lot shall be selected and tensile tested)																
Sample # →	1	2	3	4	5	6	7	8	9	10	Avg	St Dev	K	Calculated Lower bound	Min Spec	Pass / Fail
Seg A	26.49	27.65	27.98	27.77	26.73	28.77	25.28	23.69	27.23	23.82	26.541	1.745301	4.378	18.9000709	8.542	PASS
Seg B	66.71	64.68	67.4	63.65	61.41	61.63	60.14	66.2	62.39	63.53	63.774	2.446218	3.981	54.0356064	8.542	PASS
Seg C	83.67	83.55	78.86	77.95	85.6	77.64	81.92	80.77	76.4	77.12	80.348	3.211538	2.911	70.9992142	8.542	PASS

All Force Values are recorded in Pound-Force and Distance is in Inches
Specification for lower bound is 38N was converted to 8.542Lbf
First Peak Force was collected during test and has been included in the raw data file (this information will not be captured / summarized in the DA due to it is not required to used for DA acceptance.

EDW Commander Flex - Bend and Tensile Strength Testing

LOT #: 500000296544

Date: 22 Jan 24

Inspector Name: Javier Olivares

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

J001 22 Jan 24