Production Order: 500000304680

Material: SA0155-01 Rev F

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

Material Type: ZFRT

Description: Edwards Flex Shaft Commander 155885

Order Type: ZSTD

Production Version: 7987

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	Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): GS05 9:30AM 06 Feb 24 Record Time Extrusions First Exit Dryer (Initial/Time/Date): KB2 2:15pm 07 Feb24 Record Dryer Shelf #: N/A	N/A	N/A	05FEB24	BV57

Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used
MM0179-01	D	D	PC	500	0000294700	500
					N/A	N/A
MM1536-01	B	B	PC	500	0000290560	500

Notes: DA2484, 2564
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

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Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
							N/A	N/A				
		RM0158-01	E	E	PC	200	88018	200				
							N/A	N/A				
		1000-1153-01	A	A	PC	594	89090 89092 88694	200 200 200				
		1000-2053-01	A	A	PC	500	0000287543	500				
							N/A	N/A				
N/A	N/A	MM1537-02	A	A	PC	500	0000288401	500	N/A	N/A	N/A	N/A
							N/A	N/A				
		TL0167-02	E	E	PC	70	N/A	Bulk				
							N/A	Bulk				
		TL0165-05	J	J	PC	5	N/A	Bulk				
							N/A	Bulk				
		TL0165-03	J	J	PC	5	N/A	Bulk				
							N/A	Bulk				

Notes: N/A
N/A
N/A

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Production Order: 500000304680

Material: SA0155-01 Rev F

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Production Order Qty: 500 PC
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Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	141967-01	02	02	PC	500	D ~~88399~~ 85794 ~~85502~~ 88396	6 204 300	N/A	N/A	N/A	N/A
		RM7349-02	C	C	PC	543	82864 N/A	600 N/A				
		RM7348-01	C	C	PC	500	85673 N/A	500 N/A				
		RM4001-01	B	B	PC	125	88702 82817	100 25				
		RM0607-01	D	D	PC	56	78322 N/A	65 N/A				
		RM0498-01	C	C	PC	500	0000287647 N/A	482 N/A				
		RM0009-04	I	1	PC	1	88992 N/A	Bulk Bulk				
		RM0009-04	I	1	PC	1	88992	Bulk				

Notes: N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32 D KP02 08Feb24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
							N/A	Bulk				
		MM1538-01	A	A	PC	500	0000290562	500				
							N/A	N/A				
		MM1537-01	A	A	PC	1000	0000290561	1120				
							N/A	N/A				
		MM0177-01	C	C	PC	500	0000284208	500				
							N/A	N/A				
N/A	N/A	MM0180-01	E	E	PC	500	0000287541	500	N/A	N/A	N/A	N/A
							N/A	N/A				
		MM0178-01	E	E	PC	500	0000276174	500				
							0000271050	80				
		MM0176-01	D	D	PC	500	0000288413	500				
							N/A	N/A				
		MM0074-01	G	G	PC	500	0000300897	521				
							0000292833					
							① ~~0000228~~	30				

Notes: N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32 ① KP02 08Feb24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

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 Confirmation Reqd(Milestone)	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	07Feb24	V078
150	CATASY01 Catheter Assembly 1 Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly .	500	0	07Feb24	JY90 CL30 TRN SH85 SH23

Notes: N/A
N/A
N/A

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SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

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 Confirmation Reqd(Milestone)	Loading Braid Stock .	500	0	07Feb24	QS31 JY35 VO78
250	CATASY01 Catheter Assembly 1	Trim Braid Wire at Proximal End .	500	0	07Feb24	CL30

Notes: N/A
N/A
N/A

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SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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	07Feb24	~~SH23~~ ST96
350	CATASY01 Catheter Assembly 1	Load Tubing .	500	0	07Feb24	CLOS PX35 GS22

Notes:
N/A
N/A
N/A

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CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NIA	Load Tubing Confirmation Reqd(Milestone)	NIA	NIA	NIA	NIA	NIA
400	CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)	Reflow .	500	0	07Feb24	CL30 V078 ~~SP85~~
450	CATASY01 Catheter	FEP Removal .	500	0	07Feb24	SY90 Y014

Notes: NIA
NIA
NIA

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SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Assembly 1 FEP Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 In-process Inspection and Rework Confirmation Reqd(Milestone)	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 88747 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 Part #: N/A Batch #: N/A Qty: N/A	482	EW - IIII IIII II DF-1111 VD-1 SEV-1 18	07Feb24	D66 VL91 PP40 TD45
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes:
N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01 Catheter Assembly 1 Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	Remove Heat Shrink & Mandrel .	482	0	07Feb24	Y936 MV78 RS23 FB01
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly .	475	DL-~~III~~ 1 MAS-1 ~~5~~ (1) (1) 08Feb24		MM02 MR60 VA96

Notes:

MA
MA
MA

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

OP446 08Feb24

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NA	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 .	475	0	08Feb24	ML38 D429
700	CATASY01 Catheter Assembly 1 Tipping	Tipping Record Tipping Oven Information: TMI: 0571 Cal Due: 31 May24 TMI: 2083C Cal Due: 31 May24 TMI: 0346 Cal Due: 31 May24 TMI: 0936A Cal Due: 31 May24	475	0	08Feb24	ML38 RS23

Notes:

N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

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
750	CATASY01 Catheter Assembly 1 Tip Inspection/ Flash Removal Confirmation Reqd(Milestone)	Tip Inspection/ Flash Removal Material Consumed: Part #: Pm1001-01 Batch #: 88702 Qty: 10 Part #: Pm06020 Batch #: 78322 Qty: 4 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	475	0	08 Feb 24	SV46 PH59 HV36
800	CATASY01 Catheter Assembly 1	Major Mandrel Removal .	466	ACD ~~AH~~ 11 (9)	① ~~08~~ 08 Feb 24	SG88 XL91 SS44

Notes: N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

① SS44 08 Feb 24

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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. passed 2. passed 3. passed 4. passed 5. passed	464	SKV-1 EW-1 (2)	08 Feb 24	NL05 SS52
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	HT72 MV33 SH04

Notes:
N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	Re-Inspect after re-work. Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: 6700-01 Cal Due: 31 May 24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: RM4001-01 Batch #: 88702 Qty: N/A Part #: RM0607-01 Batch #: 78322 Qty: N/A Part #: 1000-1153-01 Batch #: 88694 Qty: N/A Part #: RM0158-01 Batch #: 88018 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	419	MAR-IIIIII IIII DIS-IIII ~~IIII~~ III DEL-II #605-IIII #705-1 DL-III #506-1 #606-1 EW-II #405-1 (45)	08 Feb 24	XL91 KL67 kl55 PJ46 KT47
950	QUALITY1 Quality Inspection & Review	Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: 50713B Cal Due: 12 Apr 24 Record Caliper Information:	N/A	N/A	N/A	N/A

Notes:

N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	TMI: 0733 Cal Due: 30Apr24 Record DIM02 Go/No-Go Gage Information: TMI: 0691 Cal Due: 30Sep25 TMI: 0692 Cal Due: 30Sep25 Record DIM02 Inspection Results N = 54: Pass: 54 Fail: 0	386	DIS - ~~IIII IIII IIII IIII IIII~~ STR - 11 ① ~~DIS IIII (51)~~ WK - 1 DIS - ~~IIII~~ (33)	08Feb24	XL91 KL67 0521
1000	QUALITY1 Quality Inspection & Review Quality Inspection & Review Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: 1056 Cal Due: 31 May 24 Record Length Gage Information: TMI: 0889D Cal Due: 30Sep24 Record Calibrated Ruler Information: TMI: 0629 Cal Due: 30Sep24	370	LT - ~~IIII IIII~~ IIII 1 (16)	08Feb24	XL91 KL67 5544

Notes: N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

① P146 08 Feb 24

Production Order: 500000304680

Material: SA0155-01 Rev F

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

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	349	SCR - IIII (TT) Del - III (TT) FM - II (TT) ~~SCR - II~~ SCR - I Dis - IIII VD - IIII Mar - II (21)	08Feb24	SV43
1100	CATASY01 Catheter Assembly 1 Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): KP02 08Feb24	N/A	N/A	08Feb24	KP02

Notes: N/A
N/A
N/A

Date Printed: 02/05/2024 / 19:20:32

(1) SV43 08Feb24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1100	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
1150	PACKINT1 Packing assembly Package Confirmation Reqd(Milestone)	Package Package, Label, and Ship Finished Parts	349	0	09 Feb 24	AP 10

Notes: N/A AP10 09 Feb 24

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000304680

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Batch Number:	0000304680
By:	APW
Date:	09 Feb 24

Reviewed By: RBZ9
Date: 09feb24

Notes: N/A APW 09 Feb 24

Date Printed: 02/05/2024 / 19:20:32

SA0155-01

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Extend to 30Dec2024 J238 U/S/23
Extend to 19Feb2024 J238 1/Nov/2023 J238 Yr 2024

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DEVIATION AUTHORIZATION NUMBER: 2484

*See attached email extension to 24SEP23 TSD 24AUG23

Extend to 22Nov2023 J238 19/09/23

Extend to 20Dec2023 J238 11/27/2023

DEVIATION AUTHORIZATION FORM Extend to 23Oct2023 J238 21Sep

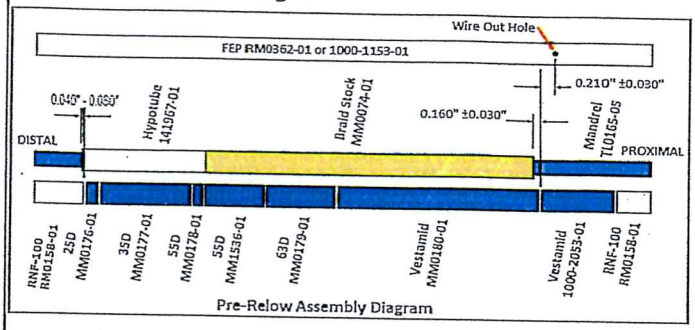
Requestor Name: Udhesh Kapadnis

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.



Pre-Relow Assembly Diagram

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.

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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

Risk Assessment:

Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:

Control Plans ☐ Yes ☒ No **FMEA's** ☐ Yes ☒ No **Validations** ☐ Yes ☒ No

Details (if any): N/A

If yes to any of the above, what controls are being put in place to mitigate the risk.

Corrective Action Required:	☐ Yes ☒ 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:	☒ Yes ☐ No	If no, explain:

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

① UK55, 23JW 2023

CREGANNA MEDICAL is part of TE

DA | 2484 ~~2468~~ ①

Group Training Record

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

Procedure:

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- 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~~ ① fixture for inspection. (See image 1)

① MM1536-01 typo correction TS12 10AUG23

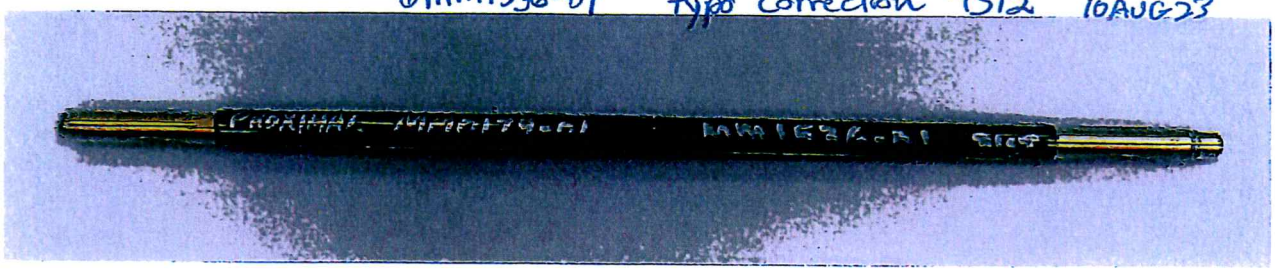

Image- 1

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)

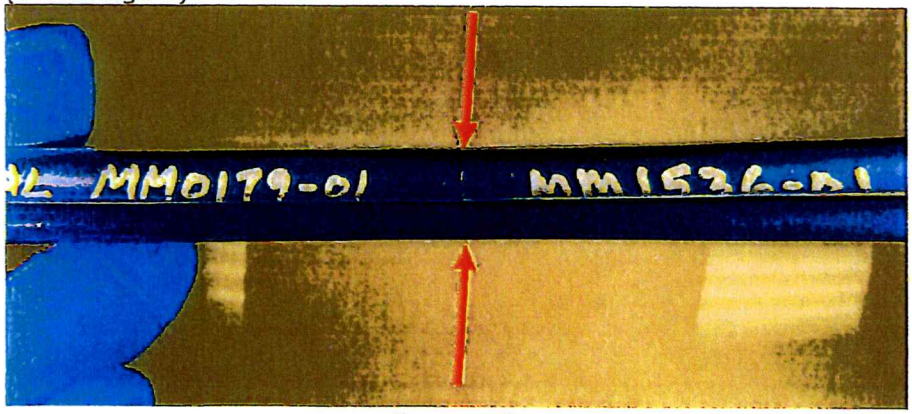

Image- 3

- 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.

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)

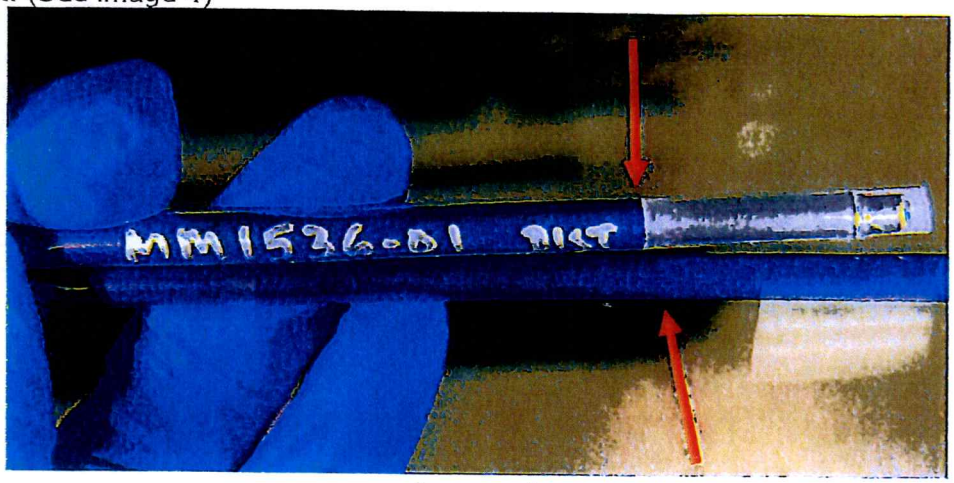

Image- 4

- 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.

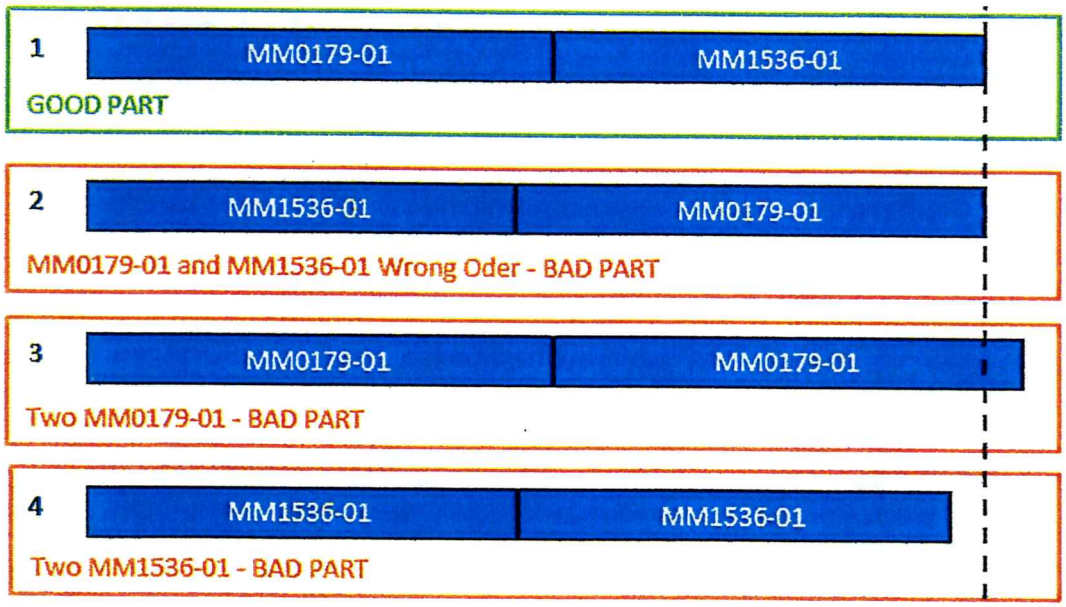

Image – 5

Extd to 14 Jan 2024 1228 12/12/2023
Extd to 13 Feb 2024 1228 1/9/24

CREGANNA MEDICAL is part of TE

CONTROLLED COPY **DEVIATION AUTHORIZATION NUMBER: DA2564**

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 ☐ Yes ☒ No **FMEA's** ☐ Yes ☒ No **Validations** ☐ Yes ☒ 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: ☐ Yes ☒ 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: ☒ Yes ☐ 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

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

PRODUCTION ORDER# 500000304680

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	11:49 pm	430	SH85	07Feb24	12:01Am	415	SH85	08Feb24	16
Tm10942	44	12:14Am	427	SH85	08Feb24	12:26Am	415	SH85	08Feb24	16
Tm10942	44	12:44Am	430	SH85	08Feb24	12:56Am	415	SH85	08Feb24	16
Tm10942	44	1:08Am	427	SH85	08Feb24	1:20Am	415	SH85	08Feb24	4
					N/A					
					V078	07Feb24				

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

PRODUCTION ORDER# 50000304680

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	2:48pm	430	OS21	07Feb24	3:00pm	415	OS21	07Feb24	16
TM10942	44	4:25pm	430	JY90	07Feb24	4:37pm	415	JY90	07Feb24	16
TM10942	44	5:02pm	430	SY47	07Feb24	5:14pm	415	SY47	07Feb24	16
TM10942	44	5:25pm	427	SH85	07Feb24	5:37PM	415	SA07	07Feb24	16
TM10942	44	6:30PM	430	SH85	07Feb24	6:42PM	415	SH85	07Feb24	16
TM10942	44	6:59pm	430	SH85	07Feb24	7:11PM	415	SH85	07Feb24	16
TM10942	44	7:25PM	428	SH85	07Feb24	7:37PM	415	SH85	07Feb24	16
TM10942	44	7:56PM	429	SH85	07Feb24	8:08pm	415	V078	07Feb24	16
TM10942	44	8:52pm	430	V078	07Feb24	9:04pm	415	SY47	07Feb24	16
TM10942	44	9:35pm	430	V078	07Feb24	9:47pm	415	SY47	07Feb24	16
TM10942	44	10:25pm	430	V078	07Feb24	10:37pm	415	V078	07Feb24	16
TM10942	44	10:55pm	430	V078	07Feb24	11:07pm	415	V078	07Feb24	16

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

PRODUCTION ORDER# 500000304680

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	11:35Pm	430	SH85	07Feb24	11:47Pm	415	SH85	07Feb24	16
TM10745	44	12:05Am	428	SH85	08Feb24	12:17Am	415	SH85	08Feb24	16
TM10745	44	12:27Am	428	SH85	08Feb24	12:39Am	415	SH85	08Feb24	16
TM10745	44	1:05Am	429	V078	08Feb24	1:17Am	415	V078	08Feb24	16
						N/A V078 07Feb24				

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

PRODUCTION ORDER# 500000304680

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	4:10 pm	430	JY90	07Feb24	4:22pm	415	JY90	07Feb24	16
TM10745	44	4:41pm	430	SH85	07 Feb24	4:53pm	415	SH85	07 Feb24	16
TM10745	44	5:17pm	429	Sy47	07Feb24	5:29pm	415	Sy47	07Feb24	16
TM10745	44	6:20pm	430	CL30	07Feb24	6:32 pm	415	CL30	07Feb24	16
TM10745	44	6:44pm	428	SH85	07 Feb24	6:56Pm	415	SH85	07 Feb24	16
TM10745	44	7:14pm	430	CL30	07Feb24	7:26pm	415	CL30	07Feb24	16
TM10745	44	7:38Pm	428	SH85	07Feb24	7:50pm	415	SH85	07Feb24	16
TM10745	44	9:07pm	430	V078	07 Feb24	9:19pm	415	Sy47	07Feb24	16
TM10745	44	9:25pm	429	Sy47	07Feb24	9:37pm	415	Sy47	07Feb24	16
TM10745	44	9:50pm	① 429 ~~44~~	Sy47	07Feb24	10:02pm	415	Sy47	07Feb24	16
TM10745	44	10:14pm	429	V078	07 Feb24	10:26pm	415	V078	07 Feb24	16
TM10745	44	10:40pm	429	V078	07 Feb24	10:52pm	415	V078	07 Feb24	16

① Sy47 07Feb24

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

PO #: 500000304680 OP #: 500 Shift #: 2

Total Parts Reworked:		29	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	////	4
EW	Exposed Wire	///// ///// ///// ///// /////	25
MP	Micropores	N/A	0
SCR	Scratch	N/A	0
SKV	Skive Marks	N/A	0
VD	Voids	////	4
N/A	N/A	N/A	0
Inspected By (Sign and Date):		[signature] 07 Feb 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): ☑

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

PO #: 5000003046 80 OP #: 500 Shift #: 2nd

Total Parts Reworked:		24	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire	~~////~~ ~~////~~ ~~////~~ /	17
MP	Micropores	N/A	N/A
SCR	Scratch	///	3
SKV	Skive Marks	N/A	N/A
VD	Voids	~~////~~ //	7
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Vanmeej Lor 07 Feb 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): ☑

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

PO #: 5000003046880 **OP #: 500** **Shift #:** 2nd

Total Parts Reworked:		25	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	|	1
EW	Exposed Wire	𝍸 𝍸 𝍸 |||	18
MP	Micropores		
SCR	Scratch	N/A	
SKV	Skive Marks	PP40 07 feb24	
VD	Voids	𝍸 |	6
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		PP40 07 feb 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): ☑

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

PO #: 5000003046 80 OP #: 750 Shift #: 2nd

Total Parts Reworked:		40	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
DIM07 OS / WO	DIM07 Oversized (Window Open)	III	3
DIM07 US / WC	DIM07 Undersized (Window Closed)	~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ III	28
EH	Exposed Hypotube	~~IIII~~ IIII	9
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		SV46 07 Feb 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: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 5000000304680 **OP #: 750** **Shift #:** 1st

Total Parts Reworked:		15	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
DIM07 OS / WO	DIM07 Oversized (Window Open)	N/A	N/A
DIM07 US / WC	DIM07 Undersized (Window Closed)	𝍸	5
EH	Exposed Hypotube	𝍸	3
N/A	Glue, Stopper	𝍸 II	7
Inspected By (Sign and Date):		PH 9, 08 Feb 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): ☑

Status CURRENT Effective 5/8/2023

CREGANNA MEDICAL is part of TE connectivity

Document No: FM5104661
Rev: B
Document Type: Manufacturing Form
Title: SA0155-01 Annealing Log Sheet Form

PRODUCTION ORDER# 500000304680

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	7:31pm	190°F	SG88	07Feb24	8:32PM	190°F	XL91	07Feb24	41
TM10409	N/A	8:37PM	190°F	SG88	07Feb24	9:47pm	190°F	SG88	07Feb24	32
TM12036	N/A	9:19pm	190°F	SG88	①07 Feb24 ~~07 Feb24~~	10:29pm	190°F	SG88	07Feb24	43
TM10409	N/A	10:06pm	190°F	SG88	07Feb24	11:16pm	190°F	SG88	07Feb24	48
TM12036	N/A	10:47pm	190°F	SG88	07Feb24	11:57pm	190°F	SG88	07Feb24	40
TM10409	N/A	11:46Pm	190°F	SG88	07Feb24	12:56AM	190°F	SG88	08Feb24	44
TM12036	N/A	12:24AM	190°F	SG88	08Feb24	1:34AM	190°F	SG88	08Feb24	37
TM10409	N/A	12:57AM	190°F	SG88	08Feb24	2:10am	190°F	SG88	08Feb24	50
TM10409	N/A	4:20am	190°F	KISS	08Feb24	5:30am	190°F	KISS	08Feb24	34
TM10409	N/A	5:35am	190°F	SSHH	08Feb24	6:45am	190°F	SSHH	08Feb24	36
TM12036	N/A	6:00am	190°F	SSHH	08Feb24	7:10am	190°F	SSHH	08Feb24	36
TM10409	N/A	6:50am	190°F	SSHH	08Feb24	8:00am	190°F	SSHH	08Feb24	25
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

①SG88 07 Feb 24

Document No: 6102619
Rev: B
Document Type: Manufacturing Form
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 5000030468O OP #: 900 Shift #: 2nd

Total Parts Reworked:		38	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	III	3
EW	Exposed Wire	IIII	5
MP	Micropores	N/A	0
SCR	Scratch	IIII IIII IIII IIII	20
SKV	Skive Marks	N/A	0
VD	Voids	1	1
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	IIII IIII IIII	15
DIM06 OS	DIM06 OD Oversized	1	1
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		Gee H 07 Feb 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 #: 5000000304680 OP #: 900 Shift #: 2

Total Parts Reworked:		45	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	11	2
EW	Exposed Wire	𝍸 𝍸 𝍸 𝍸 111	23
MP	Micropores	N/A	N/A
SCR	Scratch	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 11	42
SKV	Skive Marks	N/A	N/A
VD	Voids	11	2
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized	N/A	
DIM09 US	DIM09 OD Undersized	HT 72 07Feb 24	
Inspected By (Sign and Date):		HT 72 07Feb 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 #: 5000003046 80 **OP #: 900** **Shift #:** 1ST

Total Parts Reworked:		46	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	II	2
EW	Exposed Wire	𝍸 𝍸 𝍸 II	17
MP	Micropores	N/A	N/A
SCR	Scratch	𝍸 𝍸 𝍸	15
SKV	Skive Marks	I	I
VD	Voids	𝍸	5
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	𝍸 I	6
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		KISS KT47 08 Feb 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): ☒

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	24.74	26.78	24.68	26.2	24	25.97	24.63	24.71	26.36	23.6	25.167	1.0786313	4.378	20.444752	8.542	PASS
Seg B	58.33	60.49	67.16	63.78	66.05	61.53	60.88	60.6	63.68	60.04	62.254	2.8166103	3.981	51.0410746	8.542	PASS
Seg C	81.7	71.79	77.9	80.31	77.75	80.43	81.18	71.96	76.4	74.41	77.383	3.6788103	2.911	66.6739831	8.542	PASS

EDW Commander Flex - Bend and Tensile Strength Testing

LOT #: 500000304680
Date: 08 FEB 24
Inspector Name: LUKASU C. TSHISHIMBI
Equipment ID: TMI0311B
Cal Due Date: 27 OCT 24

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.

08Feb24