

# Production Order: 500000292879



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

## Material: SA0254-06 Rev G

Material Type: ZFRT

Description: Printed Shaft 144C Prox End Color  
B CMDR

Order Type: ZSTD

Production Version: 7999

Project Phase:

Plant / Business Unit: 1213 / AC5

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	CATASY04  Catheter Assembly 4  Count: Yes    Prepare Materials MPI0398 Rev. AH  Line Clearance MPI0230 Rev. F  By: 145 Date: 04Jan24		500	0	04Jan24	145
100	CATASY04  Straighten First Jacket MPI0398 Rev. AH		N/A	N/A	N/A	N/A

Notes: DA2581

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Catheter Assembly 4										BK05
N/A	Straighten First Jacket	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	500	0	04Jan24	
		1000-1190-01	A A	FT	2708.350	0000289940	586.600				
	Confirmation Reqd(Milestone )					0000289941	2,555				
150	CATASY04 Catheter Assembly 4	Positioning Braid Over First Jacket MPI0398 Rev. AH Record Braid Pic Count for 15 parts below: Braid Production Lot No: 00000866487	1. 40 2. 40 3. 40 4. 40 5. 40 6. 40 7. 40 8. 40 9. 40 10. 40 11. 40 12. 40 13. 40 14. 40 15. 40					500	0	04Jan24	SP63 CX32 SF35 VJ06 MY71 (TKN) NT35 M734
	Positioning Braid Over First Jacket	If more than braid production lot is used for The build, record the braid pic count for 15 parts for the second braid production lot below. Enter N/A if only one braid production lot is used for the build.									
	Confirmation Reqd(Milestone)										

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							
		Braid Production Lot No: 0000286482	1. 40	2. 40	3. 40	4. 40	5. 40	6. 40	7. 40	8. 40	9. 40	10. 40	11. 40	12. 40	13. 40	14. 40	15. 40
		Component Number	Req'd Rev	UOM	Qty.	Batch No.	Actual Qty Used										
		MM0189-01	D D	PC	500	0000286487	142										
						0000286482	372										
		RM0096-01	F F	PC	34	8217L6	34										
						N/A	N/A										
200	CATASY04  Catheter Assembly 4	Strain Relief Reflow MPI0398 Rev. AH  Temp = 420°F 5°F Air Flow = 60 SCFH					500	0	04 Jan 24	A469  KT26 TEN M128 NT35							

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
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
N/A	Strain Relief Reflow  Confirmation Reqd(Milestone )	RM0096-01	F F	PC	167	82176	166	N/A	N/A	N/A	N/A
		MM0527-01	C C	PC	500	0000276169	500				
						0000238545	5				
250	CATASY04  Catheter Assembly 4  Position Tubing for Reflow	Position Tubing For Reflow MPI0398 Rev. A/H						500	0	04Jan24	SP63 SF35 CX32 VJ06 SX66 SS79
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
		MM0186-00	D D	PC	500	0000282491	118				
						0000275689	382				
		MM0523-03	C C	PC	500	0000276167	500				
						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	N/A	MM0524-01	B	<u>B</u>	PC	500	0000281416	500			
							N/A	N/A			
		MM0530-01	B	<u>B</u>	PC	500	00002766170	500			
							N/A	N/A			
		RM7586-02	D	<u>D</u>	PC	500	84450 83420 85002	250 9 250			
		MM0185-01	I	<u>I</u>	PC	500	0000281409	500			
							N/A	N/A	N/A	N/A	
		MM1539-01	A	<u>A</u>	PC	500	0000278969	500			
							N/A	N/A			
		TL5909-01	B	<u>N/A</u>	PC	5	N/A N/A	Bulk Bulk			
		RM016101-MED	F	<u>F</u>	PC	125	82407 N/A	125 N/A			
		MM1540-01	B	<u>B</u>	PC	500	0000284205	500			

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
300	CATASY04  Catheter Assembly 4  	Reflow MPI0398 Rev. AH  Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)					500	0	04Jan24	EEL65 SS79
	Reflow	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
		1000-1154-01	A A	PC	500	86490, 86407	100, 100			
						86485, 86406	200, 100			
350	CATASY04  Catheter Assembly 4  	Skive Heat Shrink MPI0398 Rev. AH					500	0	① 05Jan23 05Jan24	Mlob SP84 ANOO
	Skive Heat									

Notes:

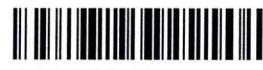
N/A

N/A

N/A

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① 1445 08 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Shrink	N/A	N/A	N/A	N/A	N/A
400	CATASY04 Catheter Assembly 4 Count: Yes 	In-Process Inspection (Visual Inspection) MPI0398 Rev. AH  FM5104693  (Rework if needed. Use FM5104983)		EW HT DF IT DISL HT AB TI IS	5 Jan 24	Mlob ANOD
	In Process Inspection	Component Number Req'd Rev Rev Used UOM Qty. Batch No. Actual Qty Used	1000-1154-01 A A PC 5 860047 5 N/A N/A	485		
450	CATASY04 Catheter Assembly 4 	Anneal Shaft MPI0398 Rev. AH FM5104692		485	0	5 Jan 24
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	Anneal Shaft	N/A	N/A	N/A	N/A	N/A
500	CATASY04  Catheter Assembly 4  	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. AH  FM5104694 FM5104695  Leak Test/Prox Cut/Ring Gage-Dim 13/21 (Rework if needed - Use FM5104983)	485	0	05Jan24	mp06
550	CATASY04  Catheter Assembly 4  	Distal Cut MPI0398 Rev. AH Line Closure MPI0230 Rev. F By: mp06 Date: 05 Jan 24	485	0	05Jan24	MB23 PK15
600	PADPRIN1  Pad Print  	Pad Print Set Up MPI0276 Rev. F	485	0	05Jan24	PK15

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
	<p>Count: Yes </p> <p>Pad Print Setup</p> <p>By: PK15 Date: 05 Jan 24</p> <p>Line Clearance F MPI0230 Rev. _____</p> <p>TMI0503 (circle TMI used) Cliché - TL0525 Ink # RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0538 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532</p> <p>TMI0735 Cliché - TL0567 Ink - RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0569 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532</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
M/A	N/A	N/A	N/A	N/A	N/A	N/A
650	PADPRIN1 Pad Print  Verification	Verification MPI0276 Rev. <u>F</u> Section 15.0	485	C	05Jan24	PK15

**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	RM7408-01	B	<u>B</u>	L	0.005	66780	0.005	N/A	N/A	N/A
		RM7409-01	B	<u>B</u>	L	0.010	85169	0.010	N/A		
700	PADPRIN1 Pad Print 	Prepare Surface for Ink MPI0276 Rev. <u>F</u> Section 15.5 Polynit wipes 99% IPA						485	0	05 Jan 24	PK15
750	PADPRIN1 Pad Print 	Print Parts MPI0276 Rev. <u>F</u> Section 20.0 Inspection gauge TMI0843						485	0	05 Jan 24	PK15
<b>Notes:</b>											
N/A											
N/A											
N/A											

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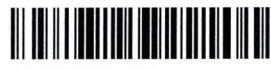
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Opr. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
800	PADPRIN1  Pad Print    In-process Inspection and Rework	In-Process Inspection and Rework MPI0276 Rev. <u>F</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	485	0	05Jan24	PK15
850	PADPRIN1  Pad Print    Curing Oven MPI0340 Rev. <u>B</u> Section 35.0  Curing oven for 120 +30/-15 minutes Parts sit for 8 hours minimum after curing oven  Lot Completion time: <u>2:30 PM</u> By: <u>PK15</u> Date: <u>05 Jan 24</u>  Confirmation Reqd(Milestone )		485	0	05Jan24	PK15
900	PADPRIN1  Pad Print	Transfer Parts to Quality MPI0276 Rev. <u>E</u> Section 40.0	N/A	N/A	N/A	N/A
Notes:						
<u>N/A</u>						
<u>N/A</u>						
<u>N/A</u>						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Transfer parts to QA  Confirmation Rreqd(Milestone )	<p>Transfer Parts to Line</p> <p>Time: <u>10:35 PM</u> By: <u>LW04</u> Date: <u>05 JAN 24</u></p> <p>TRN GL42</p>	485	0	05 JAN 24	LW04 TRN GL42
950	PADPRIN1  Pad Print  Count: Yes   Cleaning MPI0276 Rev. <u>F</u> Section 50.0  Line Clearance MPI0230 Rev. <u>F</u>  Cleaning By: <u>LW04</u> Date: <u>05 JAN 24</u>  TRN GL42  Confirmation Rreqd(Milestone )		485	0	05 JAN 24	LW04 TRN GL42
1050	QUALITY1	Required Inspection	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
1050	Quality Inspection & Review  	Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	H68	2-0AL/OS 4-54/GHC 1-VD 4-SCR 4-TT 2-FM (1) 3-FW	08 JAN 24	AJ74 CN7D KL4S SB08 AJ74
1070	CATASY04 Catheter Assembly 4    Rework Process  Confirmation	Rework MPI0398 Rev. _____  Material consumed Material _____ <i>08 Jan 24</i> Material _____ Material _____ Material _____ Material _____ Material _____ Material _____ Material _____ Material _____	H68	0	08 Jan 24	CN7D

Notes:

N/A

N/A

N/A

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CN7D 08 Jan 24

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**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1070	Reqd(Milestone) N/A	N/A	N/A	N/A	N/A	N/A
1090	QUALITY1  Quality Inspection & Review    Quality Inspection & Review  Confirmation Reqd(Milestone)	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	468	0	08Jan24	CNTD
1100	PACKINT1  Packing assembly  	Packaging Instructions SPI0087 REV. 0	468	0	08Jan24	AP10

Notes:

N/A AP10 08 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Packing Instructions  Confirmation Reqd(Milestone )	N/A 2024 08 Jan 24				

Notes:

N/A 2024 08 Jan 24

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Material: SA0254-06 Rev G

Batch Number: 0000292879

By: AG10

Date: 08 Jan 24

Reviewed By:

RB29

Date:

08 JAN 24

Notes:

N/A AG10 08 Jan 24

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## DEVIATION AUTHORIZATION FORM

Requestor Name: Geoffrey Dybicz			
Document Number Affected	Revision		
3107613	I		
<b>Deviation From:</b> MIC# Test/Specification Dimensions Sampling Equipment US100585 Distal Segment without Braid GN 6 View perpendicular to table. Pass if braid ends in "Acceptable Braid" region. Fail if braid ends in "No Braid Area" or "Must Have Braid" region. Record Summary PASS/FAIL $2.0'' \pm 0.3''$ 100% TMI0724 + Fiber Optic Light.	<b>Deviation To:</b> MIC# Test/Specification Dimensions Sampling Equipment US100585 Distal Segment without Braid GN 6 View perpendicular to table. Pass if braid ends in "Acceptable Braid" region. Fail if braid ends in "No Braid Area" or "Must Have Braid" region. Record Summary PASS/FAIL $2.0'' \pm 0.3''$ 200% TMI0724 + Fiber Optic Light. A different inspector must perform the second round of inspections. The second inspector should only inspect parts that passed the first round of inspections. Use attached form to record the results of both inspections. Notify engineering immediately if the second inspector rejects any parts.		

**Justification:** Edwards has initiated SCAR-001909 as a result of three escapes for GN6. They are now 100% inspecting for this feature, instead of AQL. In order to successfully close the SCAR, we need to eliminate any additional escapes. This deviation will be used to catch any potential escapes while permanent corrective actions are implemented.

Part Number Affected	Revision		
SA0254 - All Tabs	F		
Start Date:	End Date:	Lot Number:	
20Dec2023	31Jan2024	All Lots	
<b>Risk Assessment:</b> 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):  If yes to any of the above, what controls are being put in place to mitigate the risk			
<b>Corrective Action Required:</b> <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Change plan to follow for Document update	
<b>If no, explain:</b>		Tsix 21DEC23	
<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<b>If no, explain:</b>	
Title	Approval Name	Approval Signature	Date
Manager, Manufacturing Engineering	Jake Stanislowski		20 Dec 2023
Quality Manager	Jay Zabel		20 Dec 2023
Manager, Operations	Matthew Benson		20 Dec 2023

Deviation Authorization 2581 Secondary Inspection Record	
100% GNE Inspection #1	100% GNE Inspection #2
Inspector Initials <u>CWTO</u>	Inspector Initials <u>AJTF</u>
Date Completed <u>08-Jan-04</u>	Date Completed <u>08-Jan-04</u>
Time Completed <u>6:00 AM</u>	Time Completed <u>07:20 AM</u>
Units Passing <u>481</u>	Units Passing <u>481</u>
Units Failing <u>4</u>	Units Failing <u>0</u>

Note: 100% GNE inspection must be performed twice.

Note: The second round of inspections must be completed by a different inspector.

Inspections may not occur concurrently.

Note: Notify engineering immediately if the second inspector rejects any units.

Document No: FM5104693

Rev: C

Document Type: Manufacturing Form

Title: SA0254 In-Process Inspection Form

PRODUCTION ORDER# 50000292879

**OPER 400.0**

**In-Process Inspection (Visual Inspection)**

<b>Test/Specification</b>	<b>Dimensions</b>	<b>Sample Plan</b>	<b>Equipment</b>	<b>TMI/TL</b>	<b># Pass</b>	<b># Fail</b>	<b>Initial/Date</b>
Using a magnification light, visually inspect the entire length of the shafts.	N/A	100%	Inspect at a minimum of 2.85x magnification		500	0	ANDO 05 Jan 24
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	Inspect at a minimum of 2.85x magnification		500	0	
All other Foreign Material:	See Table	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification		500	0	
No surface damage to the shafts such as voids pits or cuts. (interior surface of distal end not included)	N/A	100%	Inspect at a minimum of 2.85x magnification		490	10	
No bumps, lumps, or protrusions along the shaft that will compromise the OD. Verify all protrusions to make sure the OD is still within specification.	N/A	100%	Inspect at a minimum of 2.85x magnification		490	0	
No flat spots, kinks, delamination, gaps between material transitions and material transitions should no exhibit cracking, no exposed or apparent braid.	N/A	100%	Inspect at a minimum of 2.85x magnification		485	5	
Measured material overflow on proximal end of stop sleeve must be $\leq 0.02"$ (i.e., $0.2 \text{ mm}^2$ dot on Tappi chart).	$\leq 0.2 \text{ mm}^2$	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	485	0	ANDO 05 Jan 24

**Document No:** FM5104983  
**Rev:** B  
**Document Type:** Manufacturing Form  
**Title:** SA0254 Cause of Rework Form

**PRODUCTION ORDER#** 500000292879

## **Attachment B: Cause of Rework.**

OPER 400.0

## **Attachment B: Cause of Rework**

OPER 500.0

**Document No:** FM5104692  
**Rev:** B  
**Document Type:** Manufacturing Form  
**Title:** SA0254 Annealing Oven Log Form

**PRODUCTION ORDER#** 500000292879

OPER 450.0

## Annealing Log Sheet

Document No: FM5104694  
 Rev: B  
 Document Type: Manufacturing Form  
 Title: SA0254 Max OD Gauge Check Form

PRODUCTION ORDER# 500000292879

**OPER 500.0**

**▲13 & ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection**

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI####XX <b>(Ex. TMI0748AC or TMI0747AD)</b>	Initials	Date	Time
Before	Dimension 13	TMI0748AM	1Y45	05Jan24	4:00 AM
Before	Dimension 21	TMI0747X	1Y45	05Jan24	4:00 AM
After	Dimension 13	TMI0748AM	1Y45	05Jan24	10:30 AM
After	Dimension 21	TMI0747X	1Y45	05Jan24	10:30 AM

Document No: FM5104695  
 Rev: C  
 Document Type: Manufacturing Form  
 Title: SA0254 Pressure Decay Testing Form

**PRODUCTION ORDER#** 500000292879

**OPER 500.0**

**Pressure Decay Testing**

<b>Test/Specification</b>	<b>Dimensions</b>	<b>Sample Plan</b>	<b>Equipment</b>	<b>TMI/TL</b>	<b># Pass</b>	<b># Fail</b>	<b>Initial/Date</b>
<b>Air Leak Test GN 15</b>	N/A	100%	Issac Pressure Decay Tester	TMI 0797B	485	0	MP06 05 Jan 24
<b>Outer Diameter ▲ 13 MAX OD at Pad Printed Area</b>  Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/-0.004" (≤0.147")	100%	Ring Gauge TMI0748	TMI 0748AM	485	0	MP06 05 Jan 24
<b>Outer Diameter ▲ 21 MAX OD</b>  Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal from stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI 0747X	485	0	MP06 05 Jan 24

Document No: FM5104983  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# \_\_\_\_\_

**OPER 1050.0**

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER

Record total quantity reworked:

Quantity Passed after Rework:

  
CN70

Rework Performed by: \_\_\_\_\_ Date: \_\_\_\_\_ Rework Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Re-Inspection Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Q L

Maximum Force Reached During Tensile Test (10 samples accepted from final inspection for each lot shall be randomly 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	EDW Commander Balloon - Bend and Tensile Strength Testing				
Seg 1	29.62	26.01	28.9	27.72	25.98	31.45	26.52	25.65	29.78	26.18	27.781	2.0322371	4.378	18.88386582	8.542	PASS	LOT #: 500000292879				
Seg B	21.52	19.98	21.03	19.4	18.51	19.05	19.71	19.16	21.79	18.68	19.883	1.1763224	4.378	14.73306043	8.542	PASS	Date: 08 JAN 2024				
Seg C	58.85	60.04	54.58	55.04	56.24	58.62	58.76	54.76	62.18	64.18	58.325	3.2405049	4.378	44.1380694	8.542	PASS	Inspector Name: KOCK YU LEE				
Equipment ID: TMI0311B Cal Due Date: 27 OCT 2024																					

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 not being required for DA acceptance.

KINK TEST AND BEND TEST PERFORMED .

Kockyulee

08 JAN 24