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The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-535

DOCUMENT TITLE: ZIP ACE Modified, 6-Pack Ship Test Report, T=0

DOCUMENT NOTES:

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Document Number: ENG-RPT-535 **Revision:** 001
Title: ZIP ACE Modified, 6-Pack Ship Test Report, T=0

All dates and times are in Mountain Standard Time.

Zip ACE Mod T=0 Ship testing

Change Request

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		07 Feb 2018, 10:05:07 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	14 Jun 2018, 06:18:53 PM	Complete
Paul Borgmeier (PBORGMEIER)		18 Jun 2018, 09:50:12 AM	Complete
Darlene Hull (DHULL)	Regulatory	18 Jun 2018, 10:56:54 AM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	19 Jun 2018, 01:36:40 PM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		19 Jun 2018, 01:46:38 PM	Complete

RA-Approval

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Darlene Hull (DHULL)	Regulatory	19 Jun 2018, 02:52:08 PM	Approved

QA-Approval

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Joni Stegeman (JSTEGEMAN)	Ethicon Quality	19 Jun 2018, 04:06:01 PM	Approved

ENG-Approval

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Paul Borgmeier (PBORGMEIER)		21 Jun 2018, 03:30:51 PM	Approved

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Lucy Richards (LRICHARDS)		22 Jun 2018, 09:16:38 AM	Approved

Final Release

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Lucy Richards (LRICHARDS)		22 Jun 2018, 09:16:50 AM	Approved

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Authored By: Tyler Skinner

1. ABSTRACT

Test Protocol ENG-PRT-441 was completed successfully. Testing was limited to Bubble Leak testing, Dye testing, Burst testing, Minimum Seal Width testing, and a Product Damage Inspection in order to verify the proposed 6-Pack shipping configuration. All tests were completed successfully.

These results demonstrate that the proposed 6-Pack shipping configuration (ME725M1C and ME725M1E) does not damage the Tyvek pouch seal and protects the product from damage. The results also provide confidence that the product will withstand the anticipated shipping environment and meet DMR requirements in ENG-DMR-012 after EO Sterilization.

2. REFERENCES

ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-PRT-441	ZIP ACE Modified, 6-Pack Ship Test, T=0
ME725M1C	Ace Blade 700, 2.5” Zip Pen, “C” Connector, 10 ft. Tubing
ME725M1E	Ace Blade 700, 2.5” Zip Pen, EC Connector, 10 ft. Tubing

3. OBJECTIVE

This Test Report documents that using the proposed 6-Pack shipping configuration to distribute Zip Pens has no effect on the packaging integrity of the EO sterile product.

4. APPENDICES

Appendix I – 2X EO Exposure
Appendix II – Preconditioning and Ship Testing
Appendix III – Bubble Leak Testing
Appendix IV – Dye Testing
Appendix V – Burst Testing
Appendix VI – Minimum Seal Width Testing
Appendix VII – Product Damage Inspection

5. RESULTS

5.1. 2X EO Sterilization

36 Zip Pen samples (6 boxes) SKU: ME725M1C Lot # 170323 were EO sterilized twice per Sterigenics Cycle 115. See Appendix I for EO sterilization documentation.

5.2. Ship Conditioning

36 Zip Pen Samples (6 boxes) SKU: ME725M1C Lot # 170323 were then ship conditioned/tested as outlined in ENG-PRT-441. See Appendix II for a complete summary of testing.

Tests were performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C
Relative Humidity: 50% ±35%

5.2.1. Preconditioning

Preconditioning followed the schedule below (see Appendix II for Cycle Data):

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to55°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 55°C to 55°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 95%RH	4 hours
Transition from 55°C and 95% RH to 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 15%RH	4 hours
Transition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

5.2.2. Manual Handling - Manual (Drop Test)

The Manual Handling (Drop Test) was performed using a drop height of 15 in as outlined in ENG-PRT-441.

5.2.3. Vehicle Stacking (Compression Test)

The Vehicle Stacking (Compression Test) was performed using a computed load (L) of 200 lb as outlined in ENG-PRT-441.

5.2.4. Vehicle Vibration and Loose Load Vibration Tests

The Vehicle Vibration test was performed for 10 min as outlined in ENG-PRT-441. Following the Vehicle Vibration test, the Loose Load Vibration Test was performed for 40 min as outlined in ENG-PRT-441.

5.2.5. Concentrated Impact Test

The Concentrated Impact Test was performed as outlined in ENG-PRT-441.

5.2.6. Manual - Handling (2nd Drop Test)

The Manual Handling (2nd Drop Test) was performed using a drop height of 15 in with the final drop at a height of 30 in as outlined in ENG-PRT-441.

5.2.7. Each box remained intact and did not break open during the test. See Appendix II.

5.3. Bubble Leak Testing

The Bubble Leak test was performed on 35 samples as outlined in ENG-PRT-441. There will no tears, holes, or open seals in any pouch. See Appendix III.

5.4. Dye Testing

The Dye Test was performed on 35 samples as outlined in ENG-PRT-441. There were no breaches in the seal and no signs of separation or degradation. See Appendix IV.

5.5. Burst Testing

The Burst Test was performed on 36 samples as outlined in ENG-PRT-441. All samples passed with a minimum of 23.1 in. H_2O and a mean of 26.625 in. H_2O. See Appendix V.

5.6. Minimum Seal Width Testing

The Minimum Seal Width Test was performed on 35 samples as outlined in ENG-PRT-441. The minimum seal width of all edges exceeded the passing criteria of 0.20” with an average of 0.31”and a minimum of 0.21”. See Appendix VI.

5.7. Product Damage Inspection

Product Damage Inspection was performed on 35 samples as outlined in ENG-PRT-441. No damage to the electrode, coating, or any other part of the Zip Pen was observed. See Appendix VII.

6. DISCUSSION

6.1. 2X EO Sterilization

6.1.1. Products were EO sterilized as outlined in the test protocol.

6.2. Ship Test Conditioning

6.2.1. Shipping and storage conditions reached all extremes required by the test protocol for all test groups.

6.2.2. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.3. Bubble Leak Testing

6.3.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.4. Dye Testing

6.4.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.5. Burst Testing

6.5.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.5.2. For Burst Testing a total of 36 samples were tested. This deviates from the required 35, however, this is acceptable as passing results were obtained for all samples and the testing of an extra sample provides an additional opportunity for a packaging failure.

6.6. Minimum Seal Width Testing

6.6.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.7. Product Damage Inspection

6.7.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

7. CONCLUSIONS

7.1. 2X EO Sterilization

7.1.1. Product was successfully exposed to EO sterilization.

7.2. Ship Test Conditioning

7.2.1. The 6-Pack box meets ASTM D4169.

7.3. Bubble Leak Testing

7.3.1. The 6-Pack shipping configuration does not add additional risk of leaks in the product packaging.

7.4. Dye Testing

7.4.1. The 6-Pack shipping configuration does not add additional risk of breaches in the seal of the product packaging.

7.5. Burst Testing

7.5.1. The 6-Pack shipping configuration does not add additional risk of burst product packaging.

7.6. Minimum Seal Width Testing

7.6.1. The 6-Pack shipping configuration does not reduce the seal width of the product packaging.

7.7. Product Damage Inspection

7.7.1. The 6-Pack shipping configuration does not add additional risk of damage to the product.

8. RECOMMENDATIONS

Based on these test results, it is recommended that EO sterilization does not adversely affect the packaging of Zip Pens in the 6-Pack shipping configuration (ME725M1C and ME725M1E).

APPENDIX I – 2X EO EXPOSURE

1st Exposure

EO STERILIZATION

PART #	LOT #	STERILE QTY.	# OF BOXES	DATE OUT
0012M	175317	18,480	70	
0012AM	175347	18,744	71	
ACE12AM	175346	1848	7	
0014AM	175403	7920	60	
0014M	175402	10,032	76	
0012M	175465	18,480	70	
0014AM	175413	8316	63	
00374	175303	2699	54	
Dunage	~	~	14	
ENG Test	~	~	1	
ENG Test ZIP PEN			6	
PN: ME725MIC	LOT # 5170323			TS 12-20-17
ACE14AM	175405	264	2	

1st EO Exposure

PREPARERS SIGNATURE: _____ DATE: 11/9/17

P/O#: Sterigenics: 29511 Nelson: 29512 11/10/17

COMMENTS: BOX total = 492 494

PALLETS = 4

REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUBMER	DESRCRIPTION OF CHANGE	EFFECTIVE DATE
A	00-134-01	Initial Relense	2000-09-21

Printed on: 17 Oct 2017, 08:50:45 am; Printed by: :EMCKENNA

Sterigenics.

Certificate of Processing

STERIGENICS 5725 Harold Gatty Drive Salt Lake City UT 84116
TEL 801 328-9901 FAX 801 328-9951 www.sterigenics.com

R55480101

11/20/2017 15:44:19 GMT
Page 1 of 1

Customer Name: Megadyne
P.O.# 29511

Processing Facility: Salt Lake City

Work Order # 2084963
Sales Order # 1821030

Customer kits

Cycle 115

Received Date/Time: 11/10/2017 15:12:02 GMT

SO Line #	Qty	UOM	Description #1	Description #2	Pallet ID	Customer Load Number	Customer Lot No.
101.000	1	PL	Customer kits	Cycle 115	47667197	29511	NA
102.000	1	PL	Customer kits	Cycle 115	47667198	29511	NA
103.000	1	PL	Customer kits	Cycle 115	47667199	29511	NA
104.000	1	PL	Customer kits	Cycle 115	47667200	29511	NA
	4	PL	Total				

Processing Summary

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)	Total Time (Hours)
100.00	RECEVING & LOAD PREP	UNPROC	11/10/2017 15:12:02	11/10/2017 17:39:10	2.45
110.00	WAREHOUSE HOLD	HOLD	11/10/2017 17:39:10	11/17/2017 17:08:38	167.49
120.00	PRECONDITIONING	P3LANE2	11/17/2017 17:08:38	11/18/2017 20:48:38	27.67
130.00	TRANSFER TO CHAMBER	WORKAISL	11/18/2017 20:48:38	11/18/2017 21:04:18	.26
200.00	CHAMBER	CHAMBER3	11/18/2017 21:04:18	11/19/2017 05:56:00	8.86
230.00	TRANSFER TO AERATION	WORKAISL	11/19/2017 05:56:00	11/19/2017 06:36:17	.67
300.00	AERATION	AERATION6	11/19/2017 06:36:17	11/20/2017 07:40:24	25.07
350.00	TRANSFER TO WAREHOUSE	PROC	11/20/2017 07:40:24	11/20/2017 07:50:21	.17
399.00	REVIEW	PROC	11/20/2017 07:50:21	11/20/2017 07:51:58	.03

Total Usage (to nearest whole number): EO 56 LB

Quality Test Summary

Op#	Quality Test Description	Min Spec	Max Spec	Result	Pass/Fail	-------Signed By------- User	Date / Time
110.00	8 HR Hold (Nov. - Apr.)	YES	YES	YES	Pass	AESPINO ARMANDO ESPINO	11/17/2017 17:05:29 GMT
110.00	Place BI's Per Specification	19 EA	19 EA	19 EA	Pass	AESPINO ARMANDO ESPINO	11/17/2017 17:05:37 GMT
120.00	Precon. Room Temp. Specs. Met	YES	YES	YES	Pass	JMREYES JOSE REYES	11/18/2017 20:54:38 GMT
120.00	Prec. Room RH Specs. Met	YES	YES	YES	Pass	JMREYES JOSE REYES	11/18/2017 20:54:53 GMT
300.00	Aeration Temperature Specs Met	YES	YES	YES	Pass	RFREEMAN RONALD FREEMAN	11/20/2017 07:41:33 GMT
350.00	Remove BI's Post Chamber	19 EA	19 EA	19 EA	Pass	RFREEMAN RONALD FREEMAN	11/20/2017 07:50:45 GMT

The above products were processed according to the process specification requirements. All parameters reviewed were found to be in compliance with specifications.

Electronically Signed By: TONY VADNAIS
Reason: Work Order Completions

Date: 11/20/2017 15:43:13 GMT

ISO 9001 and ISO 13485 Registered

VeriCycle™

Automated Process Verification

Megadyne Medical Products, Inc.

Work Order 2084963

2017-11-19

Sterigenics.

The Global Leader in
Contract Sterilization Services

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-535
	ZIP ACE Modified, 6-Pack Ship Test Report, T=0	Revision: 001
		Page 9 of 37

VeriCycle™ Automated Process Verification

Sterigenics

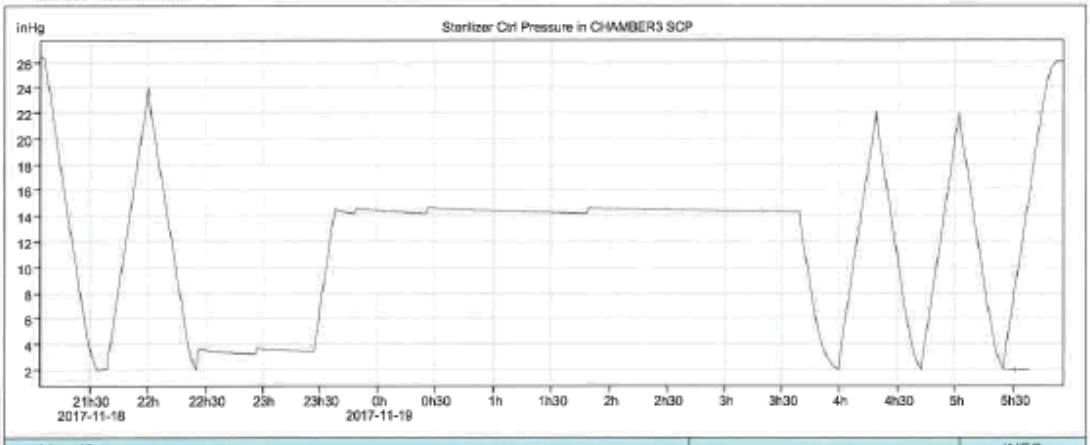
WORK ORDER:	2084963	CYCLE:	115
SALES ORDER:	1821030	PURCHASE ORDER:	29511
FACILITY:	Salt Lake City - Sterigenics 5725 Harold Gatty Drive Salt Lake City, UT 84116	CUSTOMER:	Megadyne Medical Products, Inc. 11506 South State Street Salt Lake City, UT 84020 United States
ITEM:	129_115_CH	VERIFICATION RECIPE ID:	16585

Qty	Description #1	Description #2	Pallet ID	Customer Load #	Customer Lot #
1 PL	Customer kits	Cycle 115	47667197	29511	NA
1 PL	Customer kits	Cycle 115	47667198	29511	NA
1 PL	Customer kits	Cycle 115	47667199	29511	NA
1 PL	Customer kits	Cycle 115	47667200	29511	NA
4 PL					

2017-11-10 15:12	RECEVING & LOAD PREP	UNPROC	2h27m	
parts list total quantity between 3 and 7		4		PASS
2017-11-10 17:39	WAREHOUSE HOLD	HOLD	6d23h29m	
duration at least 8h		6d23h29m		PASS
2017-11-17 17:08	PRECONDITIONING	P3LANE2	1d3h40m	
duration between 1d and 3d		1d3h40m		PASS
combi verifier				INFO
- from start of PRECONDITIONING				INFO
- until end of PRECONDITIONING				INFO
- Precon Temperatures between 100 and 120 °F				INFO
- Precon RHs between 45 and 75 %RH				INFO
- location		P3LANE2		INFO
- Precon Temperatures (PTSC)		109 .. 110 °F		INFO
- Precon Temperatures (PTSM)		109 .. 110 °F		INFO
- Precon RHs (PRHSC)		61 .. 67 %RH		INFO
- Precon RHs (PRHSM)		61 .. 67 %RH		INFO
- minimum 1d in spec		1d3h40m		PASS
- maximum 30m out of spec (consecutive)		0m		PASS
Precon Temperatures (PTSC) at most 120 °F		109 .. 110 °F		PASS
Precon Temperatures (PTSM) at most 120 °F		109 .. 110 °F		PASS
Precon RHs (PRHSC) at most 75 %RH		61 .. 67 %RH		PASS
Precon RHs (PRHSM) at most 75 %RH		61 .. 67 %RH		PASS
2017-11-18 20:48	TRANSFER TO CHAMBER	WORKAISL	16m	
duration at most 1h		16m		PASS
2017-11-18 21:04	CHAMBER	CHAMBER3	8h52m	
cycle check value must be 6115		6115		PASS

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-535
	ZIP ACE Modified, 6-Pack Ship Test Report, T=0	Revision: 001
		Page 10 of 37

VeriCycle™ Sterigenics



combi verifier				INFO
- from start of CHAMBER/VACUUM A				INFO
- until end of CHAMBER/RELEASE				INFO
- Sterilizer Temperatures between 110 and 130 °F				INFO
- location		CHAMBER3		INFO
- Sterilizer Temperatures (STSC)		117 .. 121 °F		INFO
- Sterilizer Temperatures (STSM)		117 .. 122 °F		INFO
- total time out of spec must be 0		0m		PASS
CURRENT TANK: LOT # UTLX902338K17E001266, TARE 304.0 LB				INFO
2017-11-18 21:06	VACUUM A	CHAMBER3	27m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inH_g at the end of this phase		2.0 inH_g		PASS
2017-11-18 21:34	LEAK TEST	CHAMBER3	5m	
Sterilizer Ctrl Pressure (SCP) must not increase faster than 0.2 inHg per 5m (between begin and end)		0.1 inHg/5m		PASS
2017-11-18 21:39	NITROGEN DILUTION	CHAMBER3	46m	
2017-11-18 21:39	NITROGEN	CHAMBER3	21m	
Sterilizer Ctrl Pressure (SCP) between 23.5 and 24.5 inH_g at the end of this phase		24.0 inH_g		PASS
2017-11-18 22:00	EVACUATION	CHAMBER3	25m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inH_g at the end of this phase		2.0 inH_g		PASS
2017-11-18 22:25	HUMIDIFICATION (PRESSURE)	CHAMBER3	1m	
Sterilizer Ctrl Pressure (SCP) increase between 1.0 and 2.0 inH_g		1.5 inH_g		PASS
2017-11-18 22:26	HUMIDITY DWELL (PRESS)	CHAMBER3	1h	
duration between 50m and 1h15m		1h		PASS
Sterilizer Ctrl Pressure (SCP) between 3.0 and 4.0 inH_g		3.3 .. 3.7 inH_g		PASS
2017-11-18 23:26	GAS A (EO)	CHAMBER3	12m	
duration between 5m and 55m		12m		PASS
2017-11-18 23:26	STERILANT	CHAMBER3	12m	
Sterilizer Ctrl Pressure (SCP) between 14.0 and 15.0 inH_g at the end of this phase		14.5 inH_g		PASS
2017-11-18 23:38	GAS DWELL (EO)	CHAMBER3	4h1m	
duration between 4h and 4h30m		4h1m		PASS
Sterilizer Temperatures (STSC) between 115 and 125 °F		120 .. 120 °F		PASS
Sterilizer Temperatures (STSM) between 115 and 125 °F		121 .. 121 °F		PASS
Sterilizer Ctrl Pressure (SCP) between 14.0 and 15.0 inH_g		14.2 .. 14.7 inH_g		PASS
2017-11-19 03:39	AFTER VACUUM	CHAMBER3	20m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inH_g at the end of this phase		2.0 inH_g		PASS
duration between 13m and 1h3m		20m		PASS
2017-11-19 03:59	GAS WASH A	CHAMBER3	1h25m	
duration between 1h9m and 1h43m		1h25m		PASS
2017-11-19 03:59	RELEASE	CHAMBER3	19m	
Sterilizer Ctrl Pressure (SCP) between 21.5 and 22.5 inH_g at the end of this phase		22.0 inH_g		PASS
2017-11-19 04:19	EVACUATION	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inH_g at the end of this phase		2.0 inH_g		PASS

WO2084963 page 2 of 3 printed on 2017-11-20 07:53:41

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2017-11-19 04:42	RELEASE	CHAMBER3	19m	
Sterilizer Ctrl Pressure (SCP) between 21.5 and 22.5 inHg at the end of this phase		22.0 inHg		PASS
2017-11-19 05:02	EVACUATION	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
2017-11-19 05:25	RELEASE	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 24.7 and 25.8 inHg at the end of this phase		24.8 inHg		PASS
2017-11-19 05:48	CYCLE COMPLETE	CHAMBER3	8m	
Sterilant Usage Total (SUT) at least 0 lb 5m before the start of this phase		56 lb		PASS
2017-11-19 05:56	TRANSFER TO AERATION	WORKAISL	40m	
2017-11-19 06:36	AERATION	AERATION6	1d1h4m	
duration between 1d and 3d		1d1h4m		PASS
combi verifier				INFO
- from start of AERATION				INFO
- until end of AERATION				INFO
- Aeration Temperatures between 100 and 120 °F				INFO
- Aeration Circulation between 90 and 110				INFO
- location		AERATION6		INFO
- Aeration Temperatures (ATSC)		104 .. 111 °F		INFO
- Aeration Temperatures (ATSM)		104 .. 111 °F		INFO
- Aeration Circulation (AC1)		99 .. 101		INFO
- minimum 1d in spec		1d1h4m		PASS
- maximum 30m out of spec (consecutive)		0m		PASS
Aeration Temperatures (ATSC) at most 120 °F		104 .. 111 °F		PASS
Aeration Temperatures (ATSM) at most 120 °F		104 .. 111 °F		PASS
2017-11-20 07:40	TRANSFER TO WAREHOUSE	PROC	10m	
2017-11-20 07:50	REVIEW	PROC	2m	
8 HR Hold (Nov. - Apr.) (YES)		YES		PASS
Prec. Room RH Specs. Met (YES)		YES		PASS
Precon. Room Temp. Specs. Met (YES)		YES		PASS
Aeration Temperature Specs Met (YES)		YES		PASS
Remove BI's Post Chamber (19 EA)		19		PASS
Place BI's Per Specification (19 EA)		19		PASS
RESULT OF VERIFICATION		**PASS**		

It is customers responsibility to ensure acceptance of any result other than PASS noted on this report prior to release of the load.

CERTIFICATE OF CONFORMANCE

Process Challenge Device (PCD)

Nelson Laboratories, LLC (NL) hereby certifies that the PCDs prepared conform to the requirements and quality specifications outlined in NL standard operating procedure (SOP) SOP0180.

Scope of Certification:

Product:	**NLI-PCD-010**
Batch Number:	BO 1616
Preparation Date:	24 Jul 2017
BI Manufacturer's Information:	STERIS
	Part #NA005, Lot #0397
	Exp. 08 Aug 2018
BI Type:	Spore Strip
BI Manufacturer's Spore Population:	1.4×10^6 CFU/BI
NL Verified Population:	1.9×10^6 CFU/BI
Organism:	*Bacillus atrophaeus*

Tori Dieffenbacher electronically approved — 02 Aug 2017 09:52

Released by: Tori Dieffenbacher — Date and Time

A PCD is not a surrogate for the actual product and the appropriateness of a given PCD should be determined through comparative resistance testing. This testing is performed to provide biological monitors for development of a sterilization cycle process. The validated D value for the PCD is available upon request. To confirm authenticity of this certificate, please contact NL. The most recent signature reflects the latest version of the certificate.

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123–6600 U.S.A.

Rev. 1.3.3

BO 16116

CRM42221 Rcvd: 10 Jul 2017
Ambient Use By: 08 Aug 2018

Opened: NA

STERIS

STERIS Corporation Biological Operations
***Bacillus atrophaeus* BIOLOGICAL INDICATOR CERTIFICATE OF PERFORMANCE**
Exhibit K

CATALOG NUMBER: NA005 **PRODUCT NAME: Spordex Strip**

PRODUCT LOT NUMBER: C17013 **SUBASSEMBLY LOT NUMBER: 0397**

EXPIRATION DATE: August 8, 2018

***Bacillus atrophaeus* NRRL B4418:**

Mean Population Recovery* (CFU): 1.4×10^6 Survival Time (Min.): 11.2

D_{SO} Value** (Min.***): 2.7 Kill Time (Min.): 27.3

D_{DH} Value** (Min. ***): 1.3 Survival Time (Min.): 5.4

Kill Time (Min.): 13.1

* Colony forming units determined after a preliminary heat treatment.

** 600±30mg/L EO using 100% EO, 54±1°C, 60±10% RH or 160±1°C Dry Heat

*** Determined at time of manufacture by fraction negative procedure after graded exposure to sterilization conditions.

Incubate at 30° to 35°C for seven days
Store at 2° to 24°C and between 30% to 80% RH. Do not use after the indicated expiration date.
Dispose of as you would any other microbiological waste (121°C for a minimum of 30 minutes).

This document certifies that the biological indicator product listed above meets STERIS' quality assurance specifications and the performance criteria suggested by the current revision of the United States Pharmacopeia. This certifies that the product listed above has been tested in compliance with current versions of, ISO 11138-1, ISO 11138-2, and USP.

Quality Systems Representative: [signature] Date: 4/18/17

Reviewed By: [signature] Date: 4/18/17

LIMITATION OF LIABILITY AND INDEMNITY

Nothing in this Certificate of Performance shall, or is intended to, alter, expand, or diminish the terms and conditions of sale governing your purchase of the Biological Indicator Product from STERIS. In no event, whether as a result of breach of warranty, or tort (including negligence and strict liability) shall STERIS or its suppliers be liable as a result of any statement or information contained in this Certificate of Performance. In addition, STERIS shall not be liable for any consequential or incidental damages including, without limitation, loss of use or damage to your products or equipment, cost of substitute products, or down time costs, allegedly caused by the Biological Indicators Products. The responsibility of STERIS for damages due to injuries or death caused by the Biological Indicator Product shall be limited to that portion of such damages as might be attributable to the negligence or strict liability or other tortuous conduct of STERIS.

PC600035 Revision Level: AM ECN# 71402
Effectivity Date: 03/31/2017

Page 1 of 1

STERIS Corporation • 5960 Heisley Road • Mentor, OH 44060-1834 USA • 440-354-2600

NELSON LABORATORIES

Sponsor:
Tim Kessinger
MegaDyne Medical Products, Inc.
11506 S. State St.
Draper UT 84020

Biological Indicator (BI) Sterility Test Final Report

Study Number: 1004458-S01
Test Article: Sterigenics Run #2084963
Purchase Order: 29512
Study Received Date: 20 Nov 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0079 Rev 16
Deviation(s): None

Summary: This BI sterility test was conducted to verify if any viable organisms remained on BIs used to monitor routine and/or validation cycles. All test method acceptance criteria were met.

Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

BI Information:

Type	Manufacturer	Lot #	Expiration Date	Species Name	Minimum Incubation Time	Incubation Temperature
Spore Strip	STERIS	0397	08 Aug 2018	*Bacillus atrophaeus*	7 days	30-35°C

Results:

Type	Number Tested	Number Positive	Number Negative
NLI-PCD-010	19	0	19
Environmental Control	1	0	1
Media Negative Control	1	0	1
Positive Control	1	1	0

ANAB ACCREDITED TESTING LABORATORY

Dania G. Cortes electronically approved for
Study Director — Derek L. Miller

27 Nov 2017 11:54 AM
Study Completion Date and Time

2nd Exposure

EO STERILIZATION

PART #	LOT #	STERILE QTY.	# OF BOXES	DATE OUT
0012AM	175839	8976	34	11/30/17
0012M	175803	17,160	65	
0014M	175799	2772	21	
0014MD	175648	408	2	
0012AM	175878	18,744	71	
0014AM	175985	7920	60	
0014M	175960	9108	69	
ACE36M	175989	300	6	
ACE14M	175959	180	2	
0037M	175961	2700	54	
ENG TEST	N/A		1	
ENG TEST ZIPPEN (2)			6	

w/o 2098746
004
001
001
12/19/17

2nd EO Exposure → PN: ME725MIL Lot # SP10323 TS 12.20.17

PREPARERS SIGNATURE: [signature] DATE: 11/30/17

P/O#: 29591 / 29592
Sterigenics Nelson

COMMENTS: TOTAL # 391 boxes / 4 pallets

REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUBMER	DESRCRIPTION OF CHANGE	EFFECTIVE DATE
A	00-134-01	Initial Release	2000-09-21

Printed on: 17 Oct 2017, 08:50:45 am; Printed by: :EMCKENNA.

Sterigenics.

Certificate of Processing

STERIGENICS 5725 Harold Gatty Drive Salt Lake City UT 84116
TEL 801 328-9901 FAX 801 328-9951 www.sterigenics.com

R55480101

12/10/2017 21:33:17 GMT
Page 1 of 1

Customer Name: Megadyne
P.O.# 29591

Processing Facility: Salt Lake City

Work Order # 2098746
Sales Order # 1835318

Customer kits

Cycle 115

Received Date/Time: 11/30/2017 18:03:59 GMT

SO Line #	Qty	UOM	Description #1	Description #2	Pallet ID	Customer Load Number	Customer Lot No.
101.000	1	PL	Customer kits	Cycle 115	47944534	29591	NA
102.000	1	PL	Customer kits	Cycle 115	47944535	29591	NA
103.000	1	PL	Customer kits	Cycle 115	47944536	29591	NA
104.000	1	PL	Customer kits	Cycle 115	47944537	29591	NA
	4	PL	Total				

Processing Summary

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)	Total Time (Hours)
100.00	RECEIVING & LOAD PREP	UNPROC	11/30/2017 18:03:59	11/30/2017 18:45:23	.69
110.00	WAREHOUSE HOLD	HOLD	11/30/2017 18:45:23	12/06/2017 15:14:35	140.49
120.00	PRECONDITIONING	PJLANE12	12/06/2017 15:14:35	12/07/2017 17:30:07	26.26
130.00	TRANSFER TO CHAMBER	WORKAISL	12/07/2017 17:30:07	12/07/2017 17:39:57	.16
200.00	CHAMBER	CHAMBER3	12/07/2017 17:39:57	12/08/2017 02:33:00	8.86
230.00	TRANSFER TO AERATION	WORKAISL	12/08/2017 02:33:00	12/08/2017 02:42:30	.16
300.00	AERATION	AERATION9	12/08/2017 02:42:30	12/09/2017 20:12:05	41.49
350.00	TRANSFER TO WAREHOUSE	PROC	12/09/2017 20:12:05	12/09/2017 20:48:22	.60
399.00	REVIEW	PROC	12/09/2017 20:48:22	12/09/2017 20:48:51	.01

Total Usage (to nearest whole number): EO 55 LB

Quality Test Summary

Op#	Quality Test Description	Min Spec	Max Spec	Result	Pass/Fail	Signed By - User	Signed By - Date / Time
110.00	Place Bi's Per Specification	19 EA	19 EA	19 EA	Pass	VMCINTYRE VALERIE MCINTYRE	12/06/2017 15:15:15 GMT
110.00	8 HR Hold (Nov. - Apr.)	YES	YES	YES	Pass	VMCINTYRE VALERIE MCINTYRE	12/06/2017 15:15:22 GMT
120.00	Precon. Room Temp. Specs. Met	YES	YES	YES	Pass	JMREYES JOSE REYES	12/07/2017 17:33:57 GMT
120.00	Prec. Room RH Specs. Met	YES	YES	YES	Pass	JMREYES JOSE REYES	12/07/2017 17:34:09 GMT
300.00	Aeration Temperature Specs Met	YES	YES	YES	Pass	AESPINO ARMANDO ESPINO	12/09/2017 20:13:14 GMT
350.00	Remove Bi's Post Chamber	19 EA	19 EA	19 EA	Pass	AESPINO ARMANDO ESPINO	12/09/2017 20:49:41 GMT

The above products were processed according to the process specification requirements. All parameters reviewed were found to be in compliance with specifications.

Electronically Signed By: TONY VADNAIS
Reason: Work Order Completions

Date: 12/10/2017 21:22:54 GMT

ISO 9001 and ISO 13485 Registered

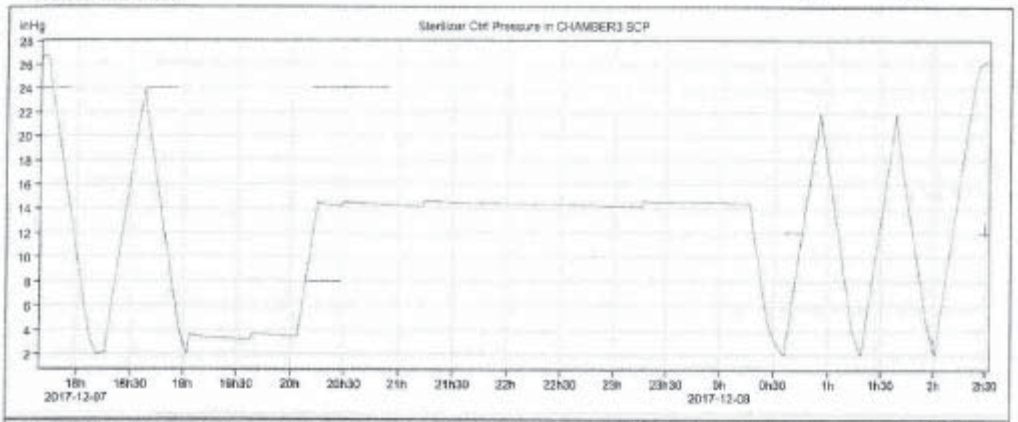
VeriCycle™ Automated Process Verification — Sterigenics

WORK ORDER:	2098746	CYCLE:	115
SALES ORDER:	1835318	PURCHASE ORDER:	29591
FACILITY:	Salt Lake City - Sterigenics 5725 Harold Gatty Drive Salt Lake City, UT 84116	CUSTOMER:	Megadyne Medical Products, Inc. 11506 South State Street Salt Lake City, UT 84020 United States
ITEM:	129_115_CH	VERIFICATION RECIPE ID:	16585

Qty	Description #1	Description #2	Pallet ID	Customer Load #	Customer Lot #
1 PL	Customer kits	Cycle 115	47944534	29591	NA
1 PL	Customer kits	Cycle 115	47944535	29591	NA
1 PL	Customer kits	Cycle 115	47944536	29591	NA
1 PL	Customer kits	Cycle 115	47944537	29591	NA
4 PL					

2017-11-30 18:03	RECEVING & LOAD PREP	UNPROC	41m	
parts list total quantity between 3 and 7		4		PASS
2017-11-30 18:45	WAREHOUSE HOLD	HOLD	5d20h29m	
duration at least 8h		5d20h29m		PASS
2017-12-06 15:14	PRECONDITIONING	P3LANE12	1d2h16m	
duration between 1d and 3d		1d2h16m		PASS
combi verifier				INFO
- from start of PRECONDITIONING				INFO
- until end of PRECONDITIONING				INFO
- Precon Temperatures between 100 and 120 °F				INFO
- Precon RHs between 45 and 75 %RH				INFO
- location		P3LANE12		INFO
- Precon Temperatures (PTSC)		109 .. 110 °F		INFO
- Precon Temperatures (PTSM)		109 .. 111 °F		INFO
- Precon RHs (PRHSC)		59 .. 67 %RH		INFO
- Precon RHs (PRHSM)		59 .. 68 %RH		INFO
- minimum 1d in spec		1d2h16m		PASS
- maximum 30m out of spec (consecutive)		0m		PASS
Precon Temperatures (PTSC) at most 120 °F		109 .. 110 °F		PASS
Precon Temperatures (PTSM) at most 120 °F		109 .. 111 °F		PASS
Precon RHs (PRHSC) at most 75 %RH		59 .. 67 %RH		PASS
Precon RHs (PRHSM) at most 75 %RH		59 .. 68 %RH		PASS
2017-12-07 17:30	TRANSFER TO CHAMBER	WORKAISL	10m	
duration at most 1h		10m		PASS
2017-12-07 17:39	CHAMBER	CHAMBER3	8h53m	
cycle check value must be 6115		6115		PASS

VeriCycle™ Sterigenics.



combi verifier				INFO
- from start of CHAMBER/VACUUM A				INFO
- until end of CHAMBER/RELEASE				INFO
- Sterilizer Temperatures between 110 and 130 °F				INFO
- location		CHAMBER3		INFO
- Sterilizer Temperatures (STSC)		118 .. 121 °F		INFO
- Sterilizer Temperatures (STSM)		119 .. 122 °F		INFO
- total time out of spec must be 0		0m		PASS
CURRENT TANK: LOT # UTLX902336L17E001930, TARE 305.0 LB				INFO
2017-12-07 17:43	VACUUM A	CHAMBER3	27m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
2017-12-07 18:11	LEAK TEST	CHAMBER3	5m	
Sterilizer Ctrl Pressure (SCP) must not increase faster than 0.2 inHg per 5m (between begin and end)		0.1 inHg/5m		PASS
2017-12-07 18:16	NITROGEN DILUTION	CHAMBER3	46m	
2017-12-07 18:16	NITROGEN	CHAMBER3	21m	
Sterilizer Ctrl Pressure (SCP) between 23.5 and 24.5 inHg at the end of this phase		24.0 inHg		PASS
2017-12-07 18:37	EVACUATION	CHAMBER3	25m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
2017-12-07 19:02	HUMIDIFICATION (PRESSURE)	CHAMBER3	1m	
Sterilizer Ctrl Pressure (SCP) increase between 1.0 and 2.0 inHg		1.5 inHg		PASS
2017-12-07 19:03	HUMIDITY DWELL (PRESS)	CHAMBER3	1h	
duration between 50m and 1h15m		1h		PASS
Sterilizer Ctrl Pressure (SCP) between 3.0 and 4.0 inHg		3.2 .. 3.8 inHg		PASS
2017-12-07 20:03	GAS A (EO)	CHAMBER3	12m	
duration between 5m and 55m		12m		PASS
2017-12-07 20:03	STERILANT	CHAMBER3	12m	
Sterilizer Ctrl Pressure (SCP) between 14.0 and 15.0 inHg at the end of this phase		14.5 inHg		PASS
2017-12-07 20:15	GAS DWELL (EO)	CHAMBER3	4h1m	
duration between 4h and 4h30m		4h1m		PASS
Sterilizer Temperatures (STSC) between 115 and 125 °F		120 .. 121 °F		PASS
Sterilizer Temperatures (STSM) between 115 and 125 °F		121 .. 122 °F		PASS
Sterilizer Ctrl Pressure (SCP) between 14.0 and 15.0 inHg		14.2 .. 14.7 inHg		PASS
2017-12-08 00:16	AFTER VACUUM	CHAMBER3	20m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
duration between 13m and 1h3m		20m		PASS
2017-12-08 00:36	GAS WASH A	CHAMBER3	1h25m	
duration between 1h8m and 1h43m		1h25m		PASS
2017-12-08 00:36	RELEASE	CHAMBER3	19m	
Sterilizer Ctrl Pressure (SCP) between 21.5 and 22.5 inHg at the end of this phase		22.0 inHg		PASS
2017-12-08 00:55	EVACUATION	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS

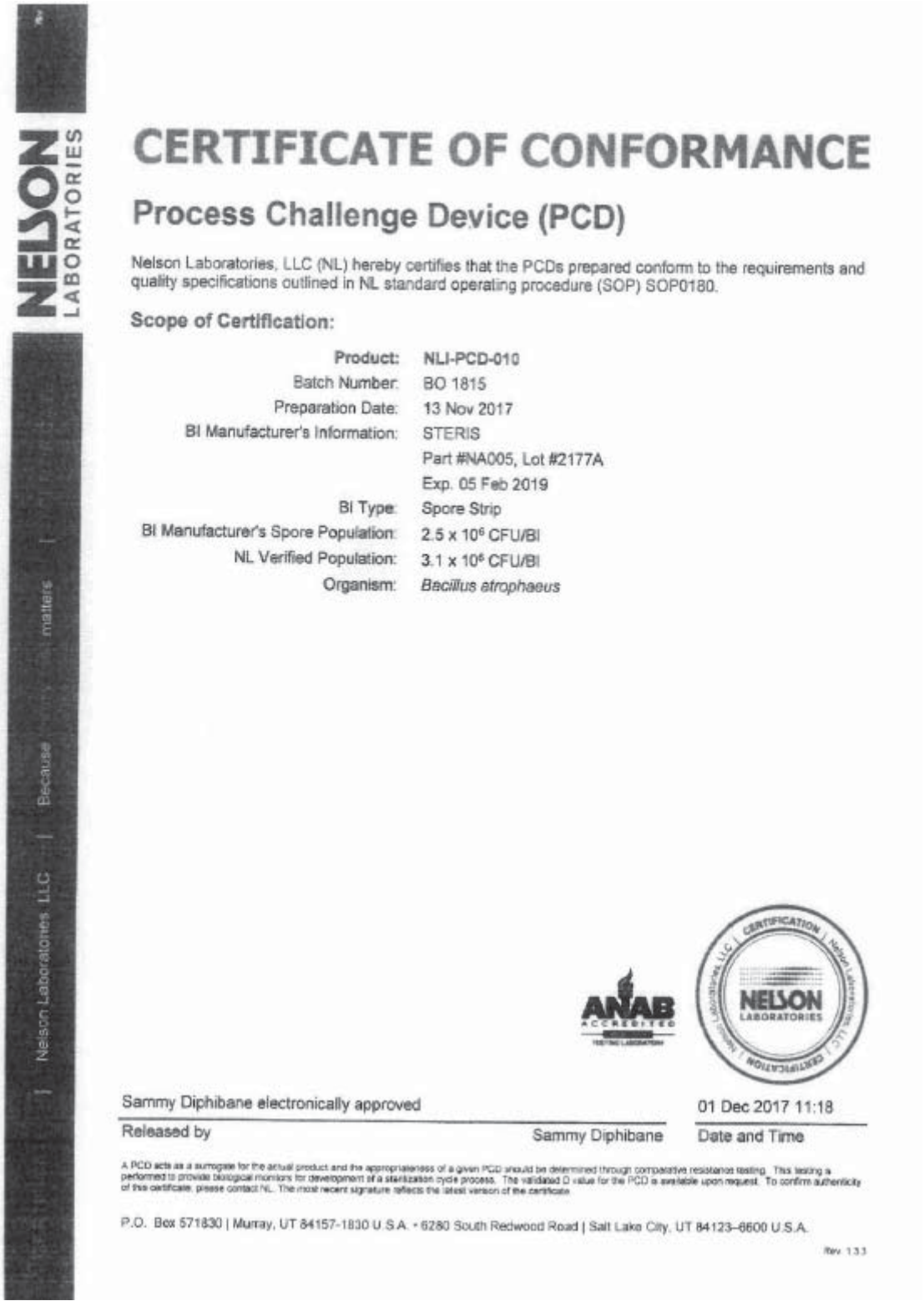
WO2098746 page 2 of 3 printed on 2017-12-09 20:50:38

VeriCycle™ Automated Process Verification — Sterigenics

2017-12-08 01:19	RELEASE	CHAMBER3	19m	
Sterilizer Ctrl Pressure (SCP) between 21.5 and 22.5 inHg at the end of this phase		22.0 inHg		PASS
2017-12-08 01:38	EVACUATION	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
2017-12-08 02:01	RELEASE	CHAMBER3	23m	
Sterilizer Ctrl Pressure (SCP) between 24.7 and 25.8 inHg at the end of this phase		24.8 inHg		PASS
2017-12-08 02:24	CYCLE COMPLETE	CHAMBER3	9m	
Sterilant Usage Total (SUT) at least 0 lb 5m before the start of this phase		55 lb		PASS
2017-12-08 02:33	TRANSFER TO AERATION	WORKAISL	10m	
2017-12-08 02:42	AERATION	AERATION9	1d17h30m	
duration between 1d and 3d		1d17h30m		PASS
combi verifier				INFO
- from start of AERATION				INFO
- until end of AERATION				INFO
- Aeration Temperatures between 100 and 120 °F				INFO
- Aeration Circulation between 85 and 115				INFO
- location		AERATION9		INFO
- Aeration Temperatures (ATSC)		98 .. 112 °F		INFO
- Aeration Temperatures (ATSM)		98 .. 112 °F		INFO
- Aeration Circulation (AC1)		96 .. 102		INFO
- minimum 1d in spec		1d17h27m		PASS
- maximum 30m out of spec (consecutive)		3m		PASS
Aeration Temperatures (ATSC) at most 120 °F		98 .. 112 °F		PASS
Aeration Temperatures (ATSM) at most 120 °F		98 .. 112 °F		PASS
2017-12-09 20:12	TRANSFER TO WAREHOUSE	PROC	36m	
2017-12-09 20:48	REVIEW	PROC	29s	
8 HR Hold (Nov. - Apr.) (YES)		YES		PASS
Prec. Room RH Specs. Met (YES)		YES		PASS
Precon. Room Temp. Specs. Met (YES)		YES		PASS
Aeration Temperature Specs Met (YES)		YES		PASS
Remove BI's Post Chamber (19 EA)		19		PASS
Place BI's Per Specification (19 EA)		19		PASS
RESULT OF VERIFICATION		**PASS**		

It is customers responsibility to ensure acceptance of any result other than PASS noted on this report prior to release of the load.

WO2098746 page 3 of 3 printed on 2017-12-09 20:50:38



NELSON LABORATORIES

CERTIFICATE OF CONFORMANCE

Process Challenge Device (PCD)

Nelson Laboratories, LLC (NL) hereby certifies that the PCDs prepared conform to the requirements and quality specifications outlined in NL standard operating procedure (SOP) SOP0180.

Scope of Certification:

Product:	NLI-PCD-010
Batch Number:	BO 1815
Preparation Date:	13 Nov 2017
BI Manufacturer's Information:	STERIS Part #NA005, Lot #2177A Exp. 05 Feb 2019
BI Type:	Spore Strip
BI Manufacturer's Spore Population:	2.5 x 10^6 CFU/BI
NL Verified Population:	3.1 x 10^6 CFU/BI
Organism:	*Bacillus atrophaeus*

ANAB ACCREDITED TESTING LABORATORY

NELSON LABORATORIES

Sammy Diphibane electronically approved — Released by: Sammy Diphibane

01 Dec 2017 11:18 — Date and Time

A PCD acts as a surrogate for the actual product and the appropriateness of a given PCD should be determined through comparative resistance testing. This testing is performed to provide biological monitors for development of a sterilization cycle process. The validated D value for the PCD is available upon request. To confirm authenticity of this certificate, please contact NL. The most recent signature reflects the latest version of the certificate.

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.

Rev. 1.3.3

Nelson Laboratories, LLC | Because matters

CRM43650 Rcvd: 18 Oct 2017
Ambient Use By: 05 Feb 2019

Opened:

STERIS

STERIS Corporation Biological Operations
***Bacillus atrophaeus* BIOLOGICAL INDICATOR CERTIFICATE OF PERFORMANCE**
Exhibit K

CATALOG NUMBER: NA005 **PRODUCT NAME: Spordex Strip**

PRODUCT LOT NUMBER: C17020 **SUBASSEMBLY LOT NUMBER: 2177A**

EXPIRATION DATE: February 5, 2019

***Bacillus atrophaeus* NRRL B4418:**

Mean Population Recovery* (CFU): 2.5 x 10^6 Survival Time (Min.): 11.9

D_{EO} Value** (Min.***): 2.7 Kill Time (Min.): 28.0

D_{DH} Value** (Min. ***): 1.6 Survival Time (Min.): 7.1

Kill Time (Min.): 16.6

* Colony forming units determined after a preliminary heat treatment.

** 600±30mg/L EO using 100% EO, 54±1°C, 60±10% RH or 160±1°C Dry Heat

*** Determined at time of manufacture by fraction negative procedure after graded exposure to sterilization conditions.

Incubate at 30° to 35°C for seven days
Store at 2° to 24°C and between 30% to 80% RH. Do not use after the indicated expiration date.
Dispose of as you would any other microbiological waste (121°C for a minimum of 30 minutes).

This document certifies that the biological indicator product listed above meets STERIS' quality assurance specifications and the performance criteria suggested by the current revision of the United States Pharmacopeia. This certifies that the product listed above has been tested in compliance with current versions of, ISO 11138-1, ISO 11138-2, and USP.

Quality Systems Representative: Linda [illegible] Date: 9/25/17

Reviewed By: [illegible] Date: 9/25/17

LIMITATION OF LIABILITY AND INDEMNITY

Nothing in this Certificate of Performance shall, or is intended to, alter, expand, or diminish the terms and conditions of sale governing your purchase of the Biological Indicator Product from STERIS. In no event, whether as a result of breach of warranty, or tort (including negligence and strict liability) shall STERIS or its suppliers be liable as a result of any statement or information contained in this Certificate of Performance. In addition, STERIS shall not be liable for any consequential or incidental damages including, without limitation, loss of use or damage to your products or equipment, cost of substitute products, or down time costs, allegedly caused by the Biological Indicators Products. The responsibility of STERIS for

PC600035 Revision Level: AN ECN# 76462 Page 1 of 1
Effectivity Date: 09/22/2017

STERIS Corporation • 5960 Heisley Road • Mentor, OH 44060-1834 USA • 440-354-2600

NELSON LABORATORIES

Sponsor:
Tim Kessinger
MegaDyne Medical Products, Inc.
11506 S. State St.
Draper UT 84020

Biological Indicator (BI) Sterility Test Final Report

Study Number: 1008255-S01
Test Article: Sterigenics Run #2098746
Purchase Order: 29592
Study Received Date: 10 Dec 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0079 Rev 16
Deviation(s): None

Summary: This BI sterility test was conducted to verify if any viable organisms remained on BIs used to monitor routine and/or validation cycles. All test method acceptance criteria were met.

Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

BI Information:

Type	Manufacturer	Lot #	Expiration Date	Species Name	Minimum Incubation Time	Incubation Temperature
Spore Strip	STERIS	2177A	05 Feb 2019	*Bacillus atrophaeus*	7 days	30-35°C

Results:

Type	Number Tested	Number Positive	Number Negative
NLI-PCD-010	19	0	19
Environmental Control	1	0	1
Media Negative Control	1	0	1
Positive Control	1	1	0

ANAB ACCREDITED TESTING LABORATORY

Derek L. Miller electronically approved
Study Director — Derek L. Miller

17 Dec 2017 03:46 PM
Study Completion Date and Time

Page 1 of 1

9. APPENDIX II - PRECONDITIONING AND SHIP TESTING

10. APPENDIX I – THERMAL CYCLE DATA

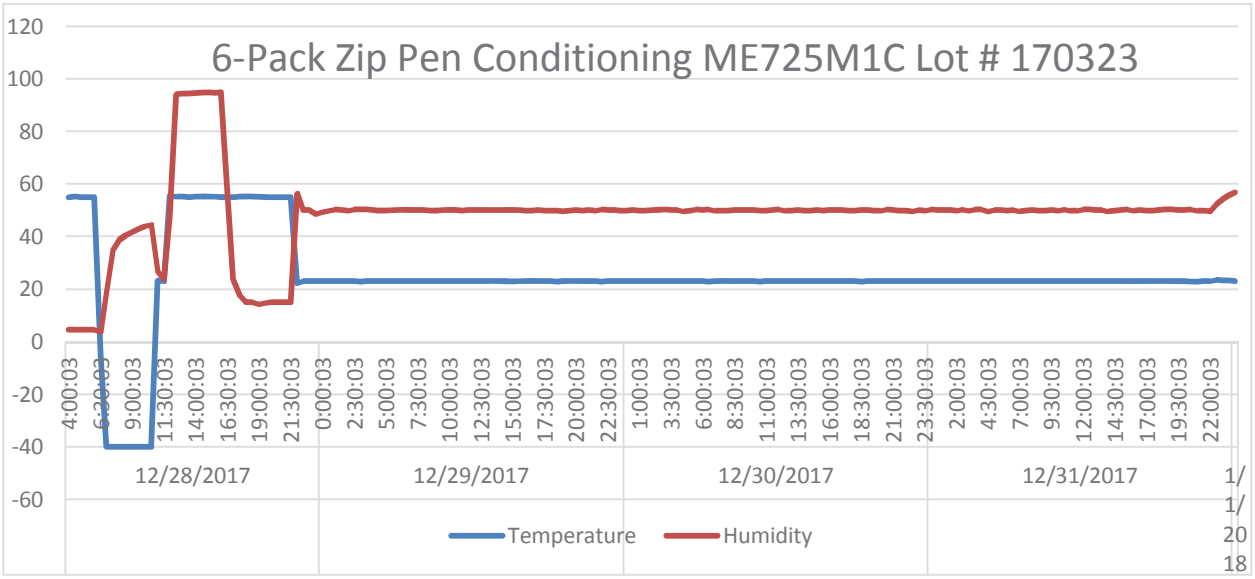
Appendix I: Thermal Cycle Data

Maximum Temperature (°C):	55.7C
Minimum Temperature (°C):	-40.1C
Maximum Temperature (%RH):	47.6%
Minimum Temperature (%RH):	43.9%
Chamber conditions held @ -40°C and no humidity control for a duration of 4 hours:	6:45 to 10:45 12/28/17 yes on 12-28-2017
Chamber conditions held @ 55°C and 95%RH for a duration of 4 hours:	12:45 to 16:45 12/28/17 yes on 12-28-2017
Chamber conditions held @ 55°C and 15%RH for a duration of 4 hours:	17:45 to 21:45 on 12/28/17 yes on 12-28-2017
Chamber conditions held @ 23°C and 50%RH for a duration of 72 hours:	22:30 on 12/28/17 to 23:59 12/31/17 yes, from 12-28-2017 to 12-31-2017.

Paul Valpreda Test Technician Name	Paul Valpreda Signature	1-12-2018 Date
Tyler Skinner Engineer Name	Tyler Skinner Signature	2.1.2018 Date
42012 Thermotron SN		5-31-2018 Calibration Due Date

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-535
	ZIP ACE Modified, 6-Pack Ship Test Report, T=0	Revision: 001
		Page 25 of 37

Graph



Raw Data

Date	Time	Air Temp	Humidity
12/28/2017	4:00:03	55	4.5
	4:30:03	55.1	4.5
	5:00:03	55	4.5
	5:30:03	55	4.5
	6:00:03	55	4.5
	6:30:03	-4.8	3.9
	7:00:03	-40	19.1
	7:30:03	-40	34.9
	8:00:03	-40	38.9
	8:30:03	-40	40.6
	9:00:03	-40	41.9
	9:30:03	-40	43
	10:00:03	-40.1	43.9
	10:30:03	-40	44.4
	11:00:03	23.2	26.6
	11:30:03	23	23.8
	12:00:03	55.7	47.6
	12:30:03	55.2	94.1
	13:00:03	55.1	94.4

	13:30:03	55	94.5
	14:00:03	55.1	94.7
	14:30:03	55.1	94.6
	15:00:03	55.1	94.8
	15:30:03	55.1	94.7
	16:00:03	55	94.8
	16:30:03	55	57.1
	17:00:03	55	23.6
	17:30:03	55.1	17.6
	18:00:03	55.1	15
	18:30:03	55.1	15.1
	19:00:03	55.1	14.4
	19:30:03	55	14.8
	20:00:03	55	15.1
	20:30:03	55	14.9
	21:00:03	55	15
	21:30:03	55	14.9
	22:00:03	22.3	56.5
	22:30:03	23	50
	23:00:03	23	50
	23:30:03	23	48.7
12/29/2017	0:00:03	23	49.4
	0:30:03	23	49.9
	1:00:03	23	50.2
	1:30:03	23	50
	2:00:03	23	49.9
	2:30:03	23	50.2
	3:00:03	22.9	50.3
	3:30:03	23.1	50.3
	4:00:03	23	50.1
	4:30:03	23	49.9
	5:00:03	23	49.9
	5:30:03	23	50.1
	6:00:03	23	50.1
	6:30:03	23	50
	7:00:03	23	50
	7:30:03	23	50
	8:00:03	23	50

	8:30:03	23.1	49.9
	9:00:03	23	49.9
	9:30:03	23	50.1
	10:00:03	23.1	50
	10:30:03	23	50
	11:00:03	23	49.8
	11:30:03	23	50.1
	12:00:03	23	50
	12:30:03	23	50
	13:00:03	23	50
	13:30:03	23	50.1
	14:00:03	23	50.1
	14:30:03	23	50
	15:00:03	22.9	50
	15:30:03	23	50
	16:00:03	23	49.8
	16:30:03	23	49.9
	17:00:03	23	50.1
	17:30:03	23	49.9
	18:00:03	23	49.8
	18:30:03	22.9	49.8
	19:00:03	23	49.7
	19:30:03	23	49.9
	20:00:03	23	50
	20:30:03	23	49.9
	21:00:03	23	50.1
	21:30:03	23	49.9
	22:00:03	22.9	50.3
	22:30:03	23	50.1
	23:00:03	23	50.1
	23:30:03	23	49.9
12/30/2017	0:00:03	23	49.9
	0:30:03	23	50
	1:00:03	23	49.9
	1:30:03	23	49.9
	2:00:03	23	50.1
	2:30:03	23	50
	3:00:03	23	50.2

	3:30:03	23	50
	4:00:03	23	50
	4:30:03	23	49.7
	5:00:03	23	49.9
	5:30:03	23	50.3
	6:00:03	23	50.1
	6:30:03	22.9	50.4
	7:00:03	23	49.9
	7:30:03	23.1	49.8
	8:00:03	23	49.9
	8:30:03	23	50
	9:00:03	23	50
	9:30:03	23	50.1
	10:00:03	23	50
	10:30:03	22.9	49.9
	11:00:03	23	49.9
	11:30:03	23	50.1
	12:00:03	23	50.4
	12:30:03	23	49.9
	13:00:03	23	49.9
	13:30:03	23	50.1
	14:00:03	23	49.8
	14:30:03	23	49.9
	15:00:03	23	50.1
	15:30:03	23	49.9
	16:00:03	23	50
	16:30:03	23	50.1
	17:00:03	23	50
	17:30:03	23	49.9
	18:00:03	23	49.8
	18:30:03	22.9	50.1
	19:00:03	23	50.1
	19:30:03	23	49.9
	20:00:03	23	49.8
	20:30:03	23	50.2
	21:00:03	23.1	50.1
	21:30:03	23	49.8
	22:00:03	23	49.9

	22:30:03	23	49.7
	23:00:03	23	50
	23:30:03	23	49.9
12/31/2017	0:00:03	23	50.3
	0:30:03	23	50
	1:00:03	23	50
	1:30:03	23	50
	2:00:03	23	49.8
	2:30:03	23	50.2
	3:00:03	23	49.9
	3:30:03	23	50.3
	4:00:03	23	50.3
	4:30:03	23	49.7
	5:00:03	23	50
	5:30:03	23	50.1
	6:00:03	23	49.9
	6:30:03	23.1	50
	7:00:03	23	49.7
	7:30:03	23	49.9
	8:00:03	23	50.1
	8:30:03	23	49.9
	9:00:03	23	49.8
	9:30:03	23	50.1
	10:00:03	23	49.9
	10:30:03	23	50.3
	11:00:03	23	49.9
	11:30:03	23	49.8
	12:00:03	23	50.2
	12:30:03	23	50.3
	13:00:03	23	50
	13:30:03	23	50
	14:00:03	23	49.6
	14:30:03	23	49.9
	15:00:03	23	50
	15:30:03	23	50.3
	16:00:03	23	49.9
	16:30:03	23	50
	17:00:03	23	49.8

	17:30:03	23	49.9
	18:00:03	23	50
	18:30:03	23	50.2
	19:00:03	23	50.3
	19:30:03	23	50.1
	20:00:03	23	50
	20:30:03	22.9	50.2
	21:00:03	22.9	49.9
	21:30:03	23	49.9
	22:00:03	23.1	49.7
	22:30:03	23.5	52.2
	23:00:03	23.4	54.3
	23:30:03	23.2	55.6
1/1/2018	0:00:03	23	56.8

11. APPENDIX II – SHIPPING TEST

Preconditioning:

Start Date: 12-28-2018 Chamber Number: 01268

Completion Date: 12-31-2018 Last Calibration: 5-23-2017

Signature/Date: Paul Valpreda 1-9-2018 Calibration due: 5-31-2018

Drop Test:

Catalog Number: ME725MIC Weight: 3.5 lbs. Drop Height: 15"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Top	Face 1	PV 1-9-18
2	Edge	Edge 5-3	PV 1-9-18
3	Edge	Edge 6-3	PV 1-9-18
4	Corner	Corner 2-3-5	PV 1-9-18
5	Corner	Corner 4-3-6	PV 1-9-18
6	Bottom	Face 3	PV 1-9-18

Comments:

Signature: Paul Valpreda Date: 1-9-2018

Compression Test:

Catalog Number: ME725MIC Pounds Force: 200

Comments: Passed.

Signature: Paul Valpreda Date: 1-9-2018

Appendix II Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials: PV

High frequency 10 minutes, Initials: PV

Completion Date: 1-9-2018

Signature: Paul Valpreda Date: 1-9-2018

Concentrated Impact Test:

Completion Date: 1-9-2018

Signature: Paul Valpreda Date: 1-9-2018

Second Drop Test:

Catalog Number: ME725MIC Weight: 3.5 lbs. Drop Height: 15"+30"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	PV 1-9-18
2	Face	Face 4	PV 1-9-18
3	Face	Face 6	PV 1-9-18
4	Corner	Corner 2-1-5	PV 1-9-18
5	Edge	Edge 2-1	PV 1-9-18
6	Bottom	Face 3, Increase height to 30 inches.	PV 1-9-18

Comments:

Signature: Paul Valpreda Date: 1-9-2018

APPENDIX III – BUBBLE LEAK TESTING

Bubble Leak Test Log Sheet For Megadyne ACE Blade 700			
Catalog - ME725M1C			
LOT - S170323			
Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26	X		
27	X		
28	X		
29	X		
30	X		
31	X		
32	X		
33	X		
34	X		
35	X		

No failures were observed - PV

Paul Valpreda — 1/10/2018
OPERATOR NAME — DATE

Paul Valpreda — 1-10-2018
OPERATOR SIGNATURE — DATE

APPENDIX IV – DYE TESTING

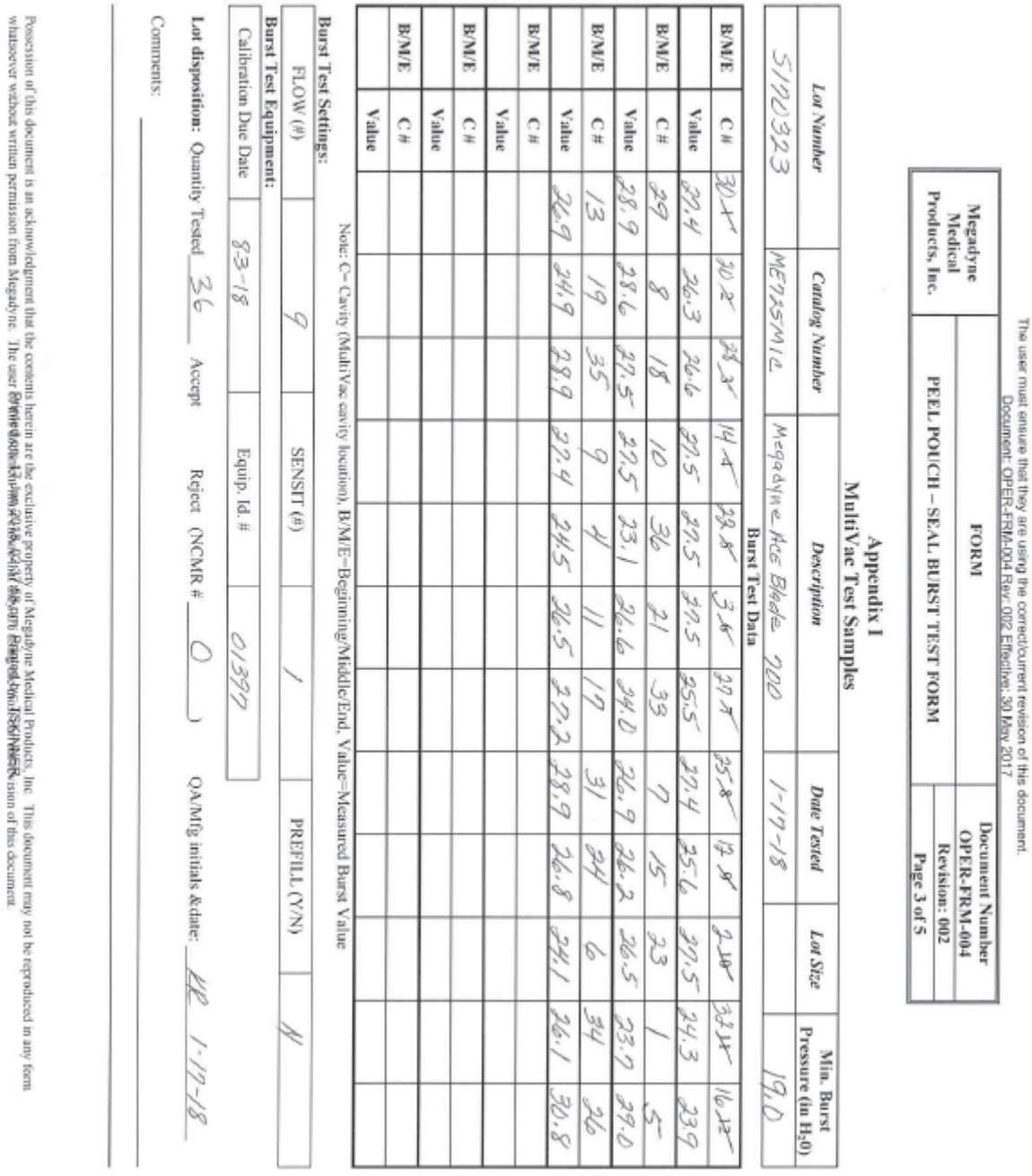
Dye Penetration Evaluation Megadyne ACE Blade 700 ME725M1C LOT S170323			
Sample #	PASS	FAIL	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26	X		
27	X		
28	X		
29	X		
30	X		
31	X		
32	X		
33	X		
34	X		
35	X		

No failures were observed - PV

Paul Valpreda — 1/11/2018
Operator Name — Date

Paul Valpreda — 1-11-2018
Operator Signature — Date

APPENDIX V – BURST TESTING



Megadyne Medical Products, Inc. | FORM: PEEL POUCH – SEAL BURST TEST FORM | Document Number: OPER-FRM-604 | Revision: 002 | Page 3 of 5

The user must ensure that they are using the correct/current revision of this document.
Document: OPER-FRM-004 Rev: 002 Effective: 30 May 2017

Appendix I
MultiVac Test Samples

Lot Number	Catalog Number	Description	Date Tested	Lot Size	Min. Burst Pressure (in H_2O)
5/22/323	MEP25M1E	Megadyne Ace Blade 220	1-17-18		19.0

Burst Test Data

B/M/E	C #	30.4	30.2	28.3	14.4	22.8	3.6	22.7	25.8	12.8	2.4	32.4	16.2								
	Value	27.4	26.3	26.6	22.5	27.5	27.5	25.5	27.4	25.6	27.5	24.3	23.9								
B/M/E	C #	29	8	18	10	36	21	33	7	15	23	1	5								
	Value	28.9	28.6	27.5	22.5	23.1	26.6	24.0	26.9	26.2	26.5	23.7	29.0								
B/M/E	C #	13	19	35	9	4	11	17	31	24	6	34	26								
	Value	26.9	24.9	28.9	22.4	24.5	26.5	22.2	28.9	26.8	24.1	26.1	30.8								
B/M/E	C #																				
	Value																				
B/M/E	C #																				
	Value																				
B/M/E	C #																				
	Value																				

Note: C= Cavity (MultiVac cavity location), B/M/E=Beginning/Middle/End, Value=Measured Burst Value

Burst Test Settings:

FLOW (#)	SENSIT (#)		PREFILL (Y/N)
9	/		N

Burst Test Equipment:

Calibration Due Date	Equip. Id. #
8-3-18	01397

Lot disposition: Quantity Tested 36 Accept Reject (NCMR # 0) QA/Mfg initials &date: LE 1-17-18

Comments:

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APPENDIX VI – MINIMUM SEAL WIDTH TESTING

Package Seal Width Evaluation
Data Collection Form

MINIMUM SEAL WIDTH EVALUATION						
Sample	Part/Lot	Cavity	Front 1	Back 3	Right 2	Left 4
1	ME725M1C LOT - S170323	2			0.32	
2	ME725M1C LOT - S170323	1			0.32	
3	ME725M1C LOT - S170323	1			0.32	
4	ME725M1C LOT - S170323	1			0.32	
5	ME725M1C LOT - S170323	1			0.31	
6	ME725M1C LOT - S170323	1			0.32	
7	ME725M1C LOT - S170323	1			0.32	
8	ME725M1C LOT - S170323	1			0.33	
9	ME725M1C LOT - S170323	2			0.30	
10	ME725M1C LOT - S170323	1			0.31	
11	ME725M1C LOT - S170323	2			0.32	
12	ME725M1C LOT - S170323	2			0.31	
13	ME725M1C LOT - S170323	2			0.32	
14	ME725M1C LOT - S170323	1			0.31	
15	ME725M1C LOT - S170323	1			0.30	
16	ME725M1C LOT - S170323	2			0.31	
17	ME725M1C LOT - S170323	2			0.32	
18	ME725M1C LOT - S170323	2			0.32	
19	ME725M1C LOT - S170323	1			0.32	
20	ME725M1C LOT - S170323	2			0.31	
21	ME725M1C LOT - S170323	1			0.31	
22	ME725M1C LOT - S170323	1			0.32	
23	ME725M1C LOT - S170323	1			0.31	
24	ME725M1C LOT - S170323	1			0.27	
25	ME725M1C LOT - S170323	2			0.21	
26	ME725M1C LOT - S170323	1			0.32	
27	ME725M1C LOT - S170323	2			0.32	
28	ME725M1C LOT - S170323	2			0.31	
29	ME725M1C LOT - S170323	1		0.31		
30	ME725M1C LOT - S170323	2	0.34			
31	ME725M1C LOT - S170323	1			0.32	
32	ME725M1C LOT - S170323	2			0.31	
33	ME725M1C LOT - S170323	2			0.31	
34	ME725M1C LOT - S170323	2		0.26		
35	ME725M1C LOT - S170323	1			0.31	

Burst Side

CALIBRATION INFORMATION
Calipers
Starrett MMP-1003

Serial Number:	723
Megadyne Number:	01039
Calibration Date:	5/18/2016
Calibration Due:	5/31/2018

Test-A-Pack Burst Test Equipment
Megadyne #01397
SN 2098
Cal date - 8-3-17
Cal due - 8-3-18

Test Fixture - Large Needle
Part #F100-1320-2
SN 478

Program:
Burst Test
Flow = 9
Sensit = 1
Prefill = Y
in H2O

Paul Valpreda — Operator Name — 1/22/2018 — Date

Paul Valpreda — Operator Signature — 1-22-2018 — Date

APPENDIX VII – PRODUCT DAMAGE INSPECTION

15. APPENDIX VI – PRODUCT DAMAGE INSPECTION

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Damage	35	Ø

Comments:
No failures were observed. No coating failures were found.

Signature: Paul Valpreda Date: 1-9-2018