



The Electrosurgical Authority®

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DOCUMENT TITLE: New Deantronics Yellow Label Stock EO Qualification

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All dates and times are in Mountain Standard Time.

ENG-RPT-581 ND Yellow Label Stock**Change Request**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)			
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst	19 Mar 2018, 08:48:59 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		19 Mar 2018, 09:21:41 AM	Complete
Darlene Hull (DHULL)	Regulatory	16 May 2018, 04:24:40 PM	Complete
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	19 Jun 2018, 06:11:01 PM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	20 Jun 2018, 09:22:17 AM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		20 Jun 2018, 01:06:18 PM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	20 Jun 2018, 03:08:00 PM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	21 Jun 2018, 04:23:16 PM	Approved

ENG-Approval

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		21 Jun 2018, 03:28:49 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		22 Jun 2018, 09:10:24 AM	Approved

Printed on: 21 Jan 2020, 11:14:56 pm; Printed by: .

Final Release

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		22 Jun 2018, 09:11:49 AM	Approved

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 1 of 36

Authored By: Tyler Skinner

1. ABSTRACT

Test Protocol ENG-PRT-465 was successfully executed. New Deantronics “Plain Label, Yellow 254x76MM” Catalog Item L100700 was subjected to 2x EO Sterilization, Pre-Conditioning, Ship Testing, and Label Clarity and Legibility as outlined in ENG-PRT-465.

The positive results contained herein provide confidence that New Deantronics “Plain Label, Yellow 254x76MM” Catalog Item L100700 can withstand the anticipated distribution environment post EO sterilization. It is anticipated that this label stock will be used with product ME725M1C (Label # 3151074-01) and ME725M1E (Label # 3151076-01).

2. REFERENCES

ME725M1C	ACE Blade 700, 2.5”, Modified, Zip Pen, “C” Connector, 10 ft. Tubing
ME725M1E	ACE Blade 700, 2.5” Modified, Zip Pen, EC Connector, 10 ft. Tubing
3151074-01	Shipping Label, Megadyne 700, Modified, 10 Foot, Standard Connector
3151076-01	Shipping Label, Megadyne 700, Modified, 10 Foot, EC Connector
ENG-PRT-465	New Deantronics Yellow Label Stock EO Qualification

3. OBJECTIVE

This Test Report provides objective evidence that New Deantronics “Plain Label, Yellow 254x76MM” Catalog Item L100700 can withstand the anticipated distribution environment post EO sterilization

4. APPENDICES

Appendix I – 2x EO Sterilization
Appendix II – Pre-Conditioning
Appendix III – Ship Testing
Appendix IV – Label Clarity and Legibility (Label Inspection)
Appendix V – Label Certificate of Compliance

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 2 of 36

5. RESULTS

As outlined in ENG-PRT-465, three labels (PN L100700 Lot # 17101101 see Appendix V) were placed on each box of product (PN ME725M1C Lot # S170324) for a total of 18 labels placed on six boxes. These boxes of product with three additional labels will be referred to as Test Samples for the remainder of this report.

5.1. 2x EO Sterilization

Six Test Samples were 2x EO Sterilized as outlined ENG-PRT-465. See Appendix I (noted as ENG TEST in EO documentation).

5.2. Preconditioning

Six Test Samples were preconditioning according to ENG-PRT-465. A summary of the preconditioning can be seen below (see Appendix II for raw cycle data):

Maximum Temperature (°C)	55.1 °C
Minimum Temperature (°C)	-40.2 °C
Maximum Humidity (%RH)	94.7%RH
Minimum Humidity (%RH)	14.4%RH
Chamber condition held at -40 °C and no humidity control for a duration of 4 hours.	12:15 to 16:15 on 3/5/18
Chamber condition held at 55 °C and 95%RH for a duration of 4 hours.	17:55 to 21:55 on 3/5/18
Chamber condition held at 55 °C and 15%RH for a duration of 4 hours.	23:45 on 3/5/18 to 3:45 on 3/6/18
Chamber condition held at 23 °C and 50%RH for a duration of 72 hours.	4:15 on 3/6/18 to 4:15 on 3/9/18

5.3. Ship Testing

The ship test was performed as outlined in ENG-PRT-465. See Appendix III for a complete summary of testing.

Tests were performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C

Relative Humidity: 50% ±35%

5.3.1. Handling - Manual (Drop Test)

The Manual Handling (Drop Test) was performed using a drop height of 15 in as outlined in ENG-PRT-465.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 3 of 36

5.3.2. Vehicle Stacking (Compression Test)

The Vehicle Stacking (Compression Test) was performed using a computed load (L) of 210 lb as outlined in ENG-PRT-465, and below.

$$L = M \times J \times ((H-h)/h) \times F$$

Where:

L is the computed load (lbf)

M = 3.5 lb

J = 1 lbf/lb

H= 108 in

h = 5.5

F = 3.0 (see section 11.2 of ASTM D4169)

This formula results in a testing weight (L) of 195.68.

Using 210 lbs. is okay as this is more weight than required by ASTM 4169. See Appendix III.

5.3.3. Vehicle Vibration and Loose Load Vibration Tests

The Vehicle Vibration test was performed for 10 min as outlined in ENG-PRT-465. Following the Vehicle Vibration test, the Loose Load Vibration Test was performed for 40 min as outlined in ENG-PRT-465.

5.3.4. Concentrated Impact Test

The Concentrated Impact Test was performed as outlined in ENG-PRT-465.

5.3.5. 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-465.

5.3.6. Each box remained intact and did not break open during the test.

5.4. Label Clarity and Legibility (Label Inspection)

All eighteen (18) labels found on the six Test Samples passed the label clarity and legibility inspection.

6. DISCUSSION

6.1. 2x EO Sterilization

Six Test Samples were 2x EO sterilized as required by ENG-PRT-465.

6.2. Preconditioning

Six Test Samples were preconditioned as required by ENG-PRT-465.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 4 of 36

6.3. Ship Testing

Six Test Samples were ship tested as required by ENG-PRT-465.

6.4. Label Clarity and Legibility (Label Inspection)

All eighteen labels (Six Test Samples) met the acceptance criteria as outlined in ENG-PRT-465.

7. CONCLUSIONS

New Deantronics “Plain Label, Yellow 254x76MM” Catalog Item L100700 meets all acceptance criteria as outlined by ENG-PRT-465.

8. RECOMMENDATIONS

New Deantronics “Plain Label, Yellow 254x76MM” Catalog Item L100700 can withstand the anticipated shipping environment post EO Sterilization and should be considered acceptable for production use.

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 5 of 36

9. APPENDIX I – 2X EO STERILIZATION

1st EO Exposure

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 01/28/2018 17:42:51 GMT
Page 1 of 1

Customer Name: Megadyne Processing Facility: Salt Lake City Work Order #: 2130113
P.O.# 29841 Sales Order #: 1988107

Customer kits Cycle 115 Received Date/Time: 01/19/2018 18:12:52 GMT

EO Line #	Qty	UOM	Description #1	Description #2	Pallet ID	Customer Load Number	Customer Lot No.
101.000	1	PL	Customer kits	Cycle 115	48563106	29841	NA
102.000	1	PL	Customer kits	Cycle 115	48563107	29841	NA
103.000	1	PL	Customer kits	Cycle 115	48563108	29841	NA
104.000	1	PL	Customer kits	Cycle 115	48563109	29841	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	01/19/2018 18:32:52	01/19/2018 18:52:29	.33
110.00	WAREHOUSE HOLD	HOLD	01/19/2018 18:52:29	01/25/2018 02:54:37	128.04
120.00	PRECONDITIONING	PLANE14	01/25/2018 02:54:37	01/26/2018 08:11:04	29.27
130.00	TRANSFER TO CHAMBER	WORKA1SL	01/26/2018 08:11:04	01/26/2018 08:17:26	.11
200.00	CHAMBER	CHAMBER3	01/26/2018 08:17:26	01/26/2018 17:09:00	8.86
230.00	TRANSFER TO AERATION	WORKA1SL	01/26/2018 17:09:00	01/26/2018 17:17:26	.14
300.00	AERATION	AERATION6	01/26/2018 17:17:26	01/27/2018 17:26:31	24.15
350.00	TRANSFER TO WAREHOUSE	PROC	01/27/2018 17:26:31	01/27/2018 19:23:09	1.94
399.00	REVIEW	PROC	01/27/2018 19:23:09	01/27/2018 19:23:31	.01
Total Usage (to nearest whole number):			EO 55 LB		

Quality Test Summary

Op#	Quality Test Description	Min Spec	Max Spec	Result	Pass/Fail	User	Date / Time
110.00	Place B's Per Specification	19 EA	19 EA	19 EA	Pass	RFREEMAN	01/25/2018 02:53:09 GMT
110.00	8 HR Hold (Nov. - Apr.)	YES	YES	YES	Pass	RFREEMAN	01/25/2018 02:53:16 GMT
120.00	Precon. Room Temp. Specs. Met	YES	YES	YES	Pass	RGILL	01/26/2018 08:12:03 GMT
120.00	Precon. Room RH Specs. Met	YES	YES	YES	Pass	RYAN GILL	01/26/2018 08:12:10 GMT
300.00	Aeration Temperature Specs Met	YES	YES	YES	Pass	RGILL	01/26/2018 08:12:10 GMT
350.00	Remove B's Post Chamber	19 EA	19 EA	19 EA	Pass	ARMANDO ESPINO	01/27/2018 17:27:37 GMT
						ESOSA	01/27/2018 19:24:26 GMT
						EFRAIN SOSA	

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 VADNANS Reason: Work Order Completions Date: 01/28/2018 17:36:57 GMT

ISO 9001 and ISO 13485 Registered

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 6 of 36



Megadyne Medical Products, Inc.
Work Order 2130115
2018-01-26



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 7 of 36

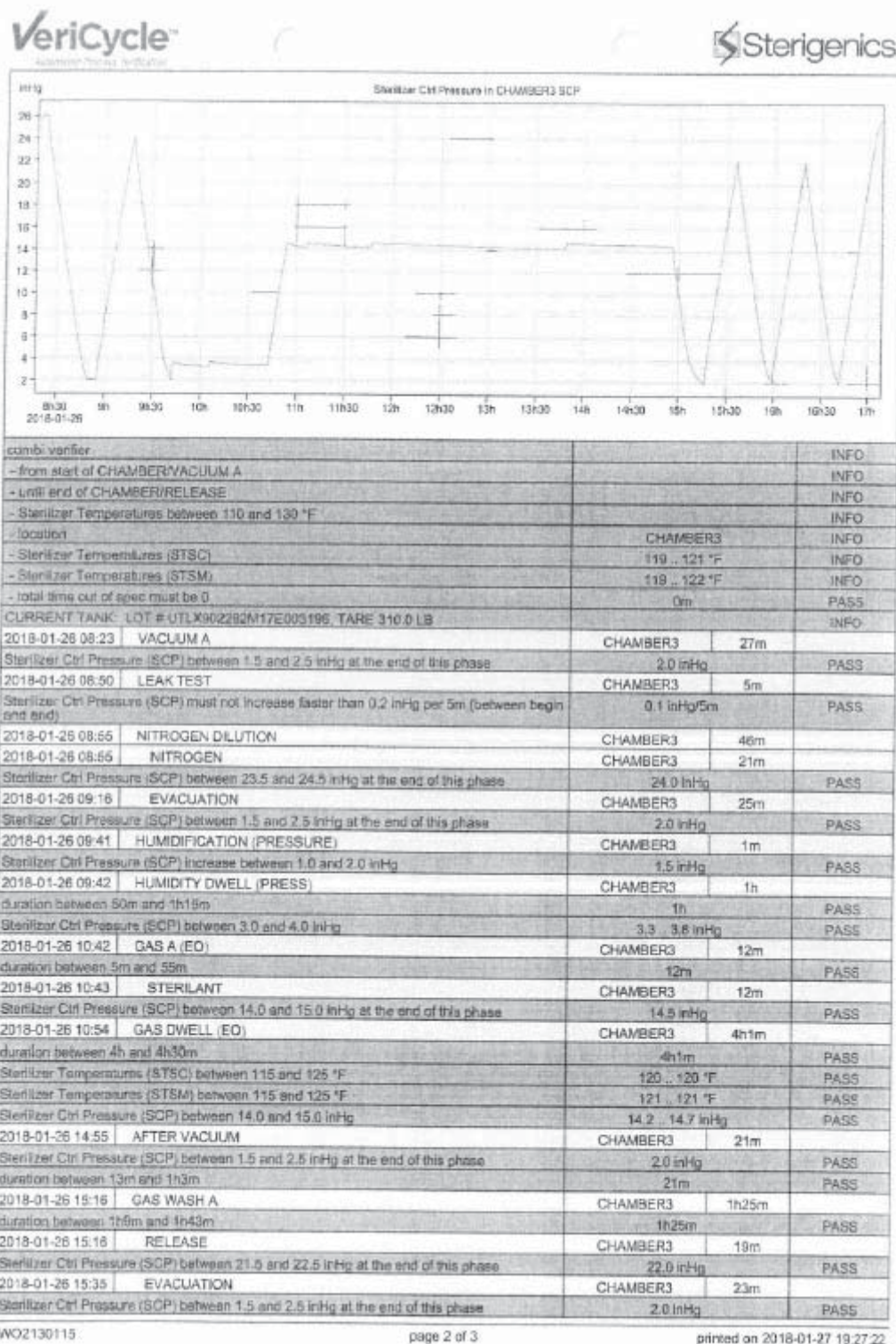


WORK ORDER: 2130115 CYCLE: 115
SALES ORDER: 1868107 PURCHASE ORDER: 29841
FACILITY: Salt Lake City - Sterigenics CUSTOMER: Megadyne Medical Products, Inc.
5725 Harold Gatty Drive 11506 South State Street
Salt Lake City, UT 84116 Salt Lake City, UT 84020
United States
ITEM: 129_115_CH VERIFICATION RECIPE ID: 18585

Qty	Description #1	Description #2	Pallet ID	Customer Load #	Customer Lot #
1 PL	Customer kits	Cycle 115	48563105	29841	NA
1 PL	Customer kits	Cycle 115	48563107	29841	NA
1 PL	Customer kits	Cycle 115	48563108	29841	NA
1 PL	Customer kits	Cycle 115	48563109	29841	NA
4 PL					

2018-01-19 18:32	RECEIVING & LOAD PREP	UNPROC	20m	
	parts list total quantity between 3 and 7	4		PASS
2018-01-19 18:52	WAREHOUSE HOLD	HOLD	5d8h2m	
	duration at least 5h	5d8h2m		PASS
2018-01-25 02:54	PRECONDITIONING	P3LANE14	1d5h15m	
	duration between 1d and 3d	1d5h15m		PASS
	control 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	P3LANE14		INFO
	- Precon Temperatures (PTSC)	109 .. 110 °F		INFO
	- Precon Temperatures (PTSM)	109 .. 110 °F		INFO
	- Precon RHs (PRHSC)	62 .. 67 %RH		INFO
	- Precon RHs (PRHSM)	62 .. 67 %RH		INFO
	- minimum 1d in spec	1d5h15m		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	62 .. 67 %RH		PASS
	Precon RHs (PRHSM) at most 75 %RH	62 .. 67 %RH		PASS
2018-01-26 08:11	TRANSFER TO CHAMBER	WORKAISL	6m	
	duration at most 1h	6m		PASS
2018-01-26 08:17	CHAMBER	CHAMBER3	8h52m	
	cycle check value must be 6115	6115		PASS

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 8 of 36



WO2130115

page 2 of 3

printed on 2018-01-27 19:27:22

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 9 of 36

VeriCycle™ <small>Autoclave Process Validation</small>		Sterigenics		
2018-01-26 15:59	RELEASE	CHAMBER3	19m	
Sterilizer Cyl Pressure (SCP) between 21.5 and 22.5 inHg at the end of this phase		22.0 inHg		PASS
2018-01-26 16:18	EVACUATION	CHAMBER3	23m	
Sterilizer Cyl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg		PASS
2018-01-26 16:41	RELEASE	CHAMBER3	23m	
Sterilizer Cyl Pressure (SCP) between 24.7 and 25.8 inHg at the end of this phase		24.8 inHg		PASS
2018-01-26 17:04	CYCLE COMPLETE	CHAMBER3	4m	
Sterilant Usage Total (SUT) at least 0.3b 5m before the start of this phase		55 lb		PASS
2018-01-26 17:09	TRANSFER TO AERATION	WORKAISI	8m	
2018-01-26 17:17	AERATION	AERATION5	1c9m	
duration between 1d and 3d		1d9m		PASS
comb 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		AERATION5		INFO
- Aeration Temperatures (ATSC)		98 .. 112 °F		INFO
- Aeration Temperatures (ATSM)		99 .. 112 °F		INFO
- Aeration Circulation (AC1)		99 .. 101		INFO
- minimum 1d in spec		1c5m		PASS
- maximum 30m out of spec (consecutive)		2m		PASS
Aeration Temperatures (ATSC) at most 120 °F		98 .. 112 °F		PASS
Aeration Temperatures (ATSM) at most 120 °F		99 .. 112 °F		PASS
2018-01-27 17:26	TRANSFER TO WAREHOUSE	PROC	1h57m	
2018-01-27 19:23	REVIEW	PROC	22s	
9 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.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 10 of 36

19 JAN'18 18:23

5725 W. Harold Gatty Rd.

Soft Lake City, UT 84116

Load Inspection Satisfactory By: FD

Routine ☒ Validation / R & D ☐


Work Order:	2130115	Sales Order:	1368107
(ABOVE FOR STERIGENICS USE ONLY)		(ABOVE FOR STERIGENICS USE ONLY)	
Customer Name:	Megadyne	Cycle #:	115
Address:	11506 South State Street	Customer Load #:	29841
City:	Draper	Billing PO #:	29841
State:	UT	Zip:	84020
"Shipping Instructions & Method Below"			

Technical Contact/#:	T. Kessinger(801)553-2810		
Logistics Contact/#:	T. Kessinger(801)553-2810		
Estimated Arrival Date:	Click here		
EO Stat Request:	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
EO Stat Form Attached:	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
Ship to Name:	Megadyne		
Address:	11506 South State Street		
City:	Draper		
State:	UT	Zip:	84020
Carrier:	Will Call	Account #	N/A
Ship. Method: Megadyne to pick own product			

PRODUCT IDENTIFICATION			
Number of Pallets:	4	Number of Cartons:	538 539
Number of Bi's / PCD's:	19/1	Number of Positive Control Bi's:	N/A
Lab Submission form attached:	YES NO		
LAL Samples:	YES NO	Number of LAL Samples to be removed:	N/A

Note: Product identification may be listed below or an attached Packing List.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 11 of 36

Product ID	# Cartons	Product ID	# Cartons
SEE ATTACHED			
HANDLING / SPECIAL INSTRUCTIONS			
Please use this E-Mail address esterilization@megadyne.com for results.			
Customer Authorization			
Signature Required for Processing:		Date:	1-18-18

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 12 of 36

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Document: OPER-FRM-016 Rev: 001 Effective: 12 Apr 2013 12:00 AM

EO STERILIZATION

PART #	LOT #	STERILE QTY.	# OF BOXES	DATE OUT
0014AM	180366	8316	63	1/18/18
0012AM	180337	8040	31	
0012M	180263	21012	80	
0013MD	180273	816	4	
0012AMD	180146	984	5	
0014AMD	180274	192	1	
0014M	180277	9360	71	
0014AM	180270	8016	61	
0012AM	180222	9264	36	
0012M	180312	18348	70	
0014M	180364	9108	69	
0012M	180322	9744	37	
ENG. TEST		—	6	
Dunnage	—	—	4	

* 0014MD 180427 192 1

PREPARERS SIGNATURE: Eric [Signature]

DATE: 1/18/18

P/O#:

COMMENTS:

4 pallets

~~536 BOXES~~ Jan-19-18

* 639 BOXES

* Updated, Added 0014MD Jan-19-18

REVISION HISTORY

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

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 13 of 36

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 1862
 Preparation Date: 18 Jan 2018
 BI Manufacturer's Information: STERIS
 Part #NA005, Lot #2837
 Exp. 10 Apr 2019
 BI Type: Spore Strip
 BI Manufacturer's Spore Population: 3.6×10^8 CFU/BI
 NL Verified Population: 3.6×10^8 CFU/BI
 Organism: *Bacillus atrophaeus*



Tori Dieffenbacher electronically approved

Released by

Tori Dieffenbacher

22 Jan 2018 13:37

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. - 5280 South Redwood Road | Salt Lake City, UT 84123-8600 U.S.A.

Rev 1.4.3

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 14 of 36



CRM44151 Rcvd: 27 Nov 2017
Ambient Use By: 10 Apr 2019

BO 1302

STERIS

Opened: _____

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

CATALOG NUMBER: NA005

PRODUCT NAME: Spordex Strip

PRODUCT LOT NUMBER: C17023

SUBASSEMBLY LOT NUMBER: 2837

EXPIRATION DATE: April 10, 2019

Bacillus atrophaeus NRRL B4418:

Mean Population Recovery* (CFU): 3.6×10^6

Survival Time (Min.): 12.4

D₉₀ Value** (Min.***): 2.7

Kill Time (Min.): 28.5

D₉₀ Value** (Min.***): 1.6

Survival Time (Min.): 7.3

Kill Time (Min.): 16.8

* 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 Thompson Date: 11/17/17

Reviewed By: Theresa J. Gaudin Date: 11/17/17

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 Indicator 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 tortious conduct of STERIS.

PC600035 Revision Level: AN ECN# 16462
Effectivity Date: 09/22/2017

Page 1 of 1

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 15 of 36



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

Biological Indicator (BI) Sterility Test Final Report

Study Number: 1017206-S01
Test Article: Sterigenics Run #2130115
Purchase Order: 29842
Study Received Date: 28 Jan 2018
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	2837	10 Apr 2019	<i>Bacillus atrophaeus</i>	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



Derek L. Miller electronically approved

Study Director

Derek L. Miller

05 Feb 2018 08:50 AM

Study Completion Date and Time

P.O. Box 571430 | Murray, UT 84157-1530 U.S.A. | 4390 South Redwood Road | Salt Lake City, UT 84123-6800 U.S.A.
www.nelsonlabs.com | Telephone 801 290 7500 | Fax 801 290 7568 | sales@nelsonlabs.com

Page 1 of 1

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 16 of 36

2nd EO Exposure

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

R55480161

02/22/2018 15:17:53 GMT
Page 1 of 1

Customer Name: Megadyne
P.O.# 39950

Processing Facility: Salt Lake City

Work Order # 2145452
Sales Order # 1984247

Received Date/Time: 02/20/2018 23:29:32 GMT

Customer kits

SO Line #	Qty	UOM	Description #1	Description #2	Pallet ID	Customer Load Number	Customer Lot No.
101.000	1	PL	Customer kits	Cycle 115	48870805	29960	NA
102.000	1	PL	Customer kits	Cycle 115	48870805	29960	NA
103.000	1	PL	Customer kits	Cycle 115	48870807	29960	NA
104.000	1	PL	Customer kits	Cycle 115	48870808	29960	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	02/09/2018 23:29:32	02/09/2018 23:32:13	.04
110.00	WAREHOUSE HOLD	HOLD	02/09/2018 23:32:13	02/19/2018 03:44:17	229.20
120.00	PRECONDITIONING	P3	02/19/2018 03:44:17	02/20/2018 10:24:28	30.50
130.00	TRANSFER TO CHAMBER	WORKA1SL	02/20/2018 10:24:28	02/20/2018 10:24:33	.05
200.00	CHAMBER	CHAMBER3	02/20/2018 10:24:33	02/20/2018 19:27:00	9.05
230.00	TRANSFER TO AERATION	WORKA1SL	02/20/2018 19:27:00	02/20/2018 19:40:57	.23
300.00	AERATION	AERATION3	02/20/2018 19:40:57	02/21/2018 20:07:49	24.45
350.00	TRANSFER TO WAREHOUSE	PROC	02/21/2018 20:07:49	02/21/2018 20:20:11	.21
399.00	REVIEW	PROC	02/21/2018 20:20:11	02/21/2018 20:23:59	.16
	Total Usage (to nearest whole number):	EO 56 LB			

Quality Test Summary

Op#	Quality Test Description	Min Spec	Max Spec	Result	Pass/Fail	User	Signed By	Date / Time
110.00	Place Bfs Per Specification	19 EA	19 EA	19 EA	Pass	RFREEMAN	RFREEMAN	02/19/2018 03:42:31 GMT
130.00	8 HR Hold (Nov. - Apr.)	YES	YES	YES	Pass	RFREEMAN	RFREEMAN	02/19/2018 03:42:44 GMT
120.00	Precon. Room Temp. Specs. Met	YES	YES	YES	Pass	RFREEMAN	RFREEMAN	02/20/2018 10:21:28 GMT
120.00	Precon. Room RH Specs. Met	YES	YES	YES	Pass	JFLORES	JFLORES	02/20/2018 10:21:35 GMT
300.00	Aeration Temperature Specs Met	YES	YES	YES	Pass	JFLORES	JFLORES	02/21/2018 20:08:52 GMT
350.00	Remove Bfs Post Chamber	19 EA	19 EA	19 EA	Pass	AESPINO	ARMANDO ESPINO	02/21/2018 20:21:24 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 Completion

Date: 02/22/2018 15:16:13 GMT

ISO 9001 and ISO 13485 Registered

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 17 of 36



Megadyne Medical Products, Inc.
Work Order 2145452
2018-02-20



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 18 of 36

VeriCycle **Sterigenics**

WORK ORDER: 2145452 CYCLE: 115
SALES ORDER: 1884247 PURCHASE ORDER: 29660
FACILITY: Salt Lake City - Sterigenics CUSTOMER: Megadyne Medical Products, Inc.
5725 Harold Gatty Drive 11506 South State Street
Salt Lake City, UT 84116 United States
ITEM: 129_115_CH VERIFICATION RECIPE ID: 16665

Qty	Description #1	Description #2	Pallet ID	Customer Lot #	Customer Lot #
1 PL	Customer kits	Cycle 115	46870805	29960	NA
1 PL	Customer kits	Cycle 115	46870806	29960	NA
1 PL	Customer kits	Cycle 115	46870807	29960	NA
1 PL	Customer kits	Cycle 115	46870808	29960	NA
4 PL					

2018-02-09 23:29	RECEIVING & LOAD PREP	UNPROC	3m	
	parts list total quantity between 3 and 7			PASS
2018-02-09 23:32	WAREHOUSE HOLD	HOLD	9d4h12m	
	duration at least 8h			PASS
2018-02-19 03:44	PRECONDITIONING	P3	1d9h36m	
	duration between 1d and 3d			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			INFO
	- Precon Temperatures (PTSC)	P3		INFO
	- Precon Temperatures (PTSM)	100 .. 110 °F		INFO
	- Precon RHs (PRHSC)	110 .. 110 °F		INFO
	- Precon RHs (PRHSM)	63 .. 67 %RH		INFO
	- minimum 1d in spec	63 .. 67 %RH		INFO
	- maximum 30m out of spec (consecutive)	1d9h36m		PASS
	Precon Temperatures (PTSC) at most 120 °F	0m		PASS
	Precon Temperatures (PTSM) at most 120 °F	100 .. 110 °F		PASS
	Precon RHs (PRHSC) at most 75 %RH	110 .. 110 °F		PASS
	Precon RHs (PRHSM) at most 75 %RH	63 .. 67 %RH		PASS
2018-02-20 10:20	TRANSFER TO CHAMBER	63 .. 67 %RH		PASS
	duration at most 1h	WORKA1SL	4m	
2018-02-20 10:24	CHAMBER	4m		PASS
	cycle check value must be 6115	CHAMBER3	9h3m	
		6115		PASS

WD2145452

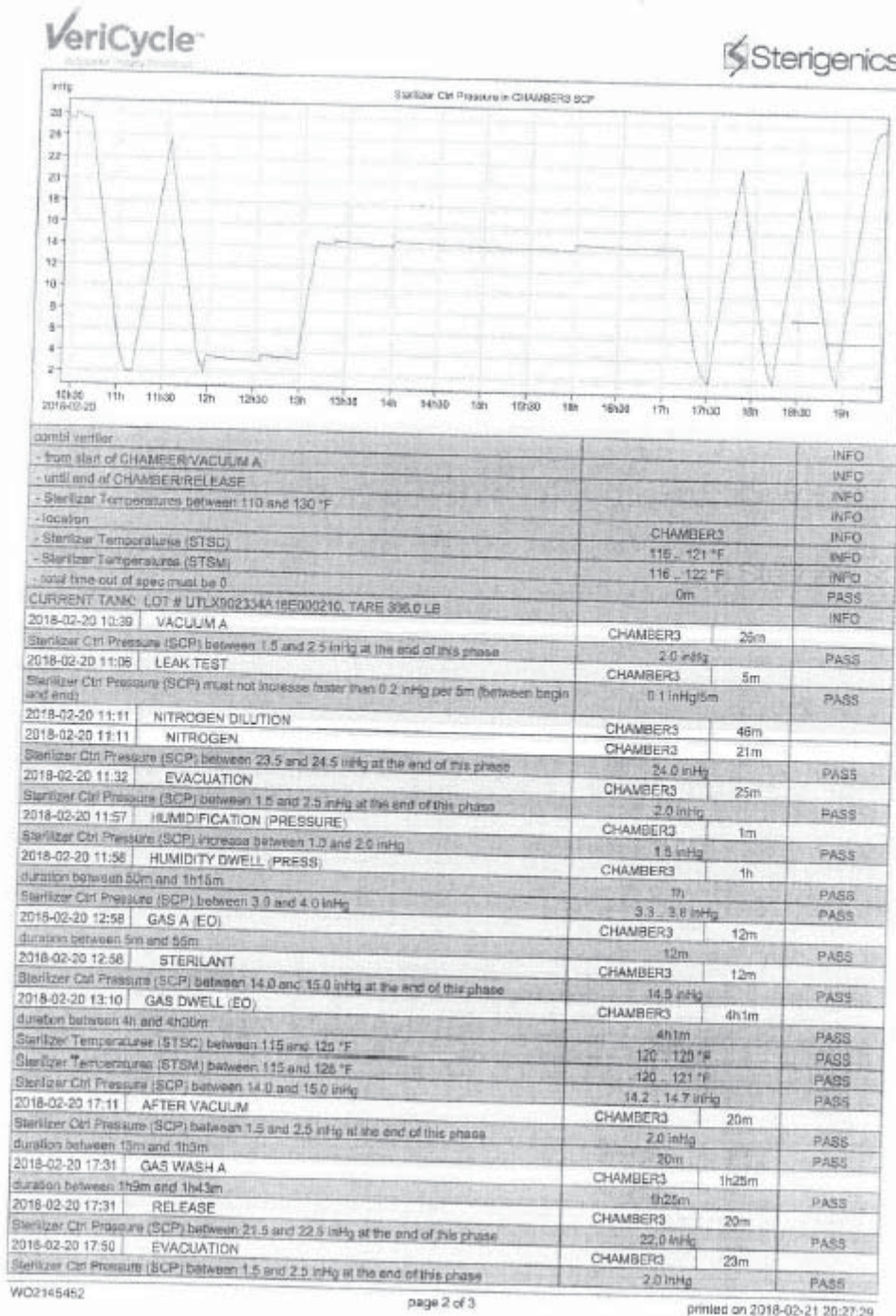
page 1 of 3

printed on 2018-02-21 20:27:29

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 19 of 36



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 20 of 36

VeriCycle Autoclave System Validation		Sterigenics	
2018-02-20 18:13	RELEASE	CHAMBER3	19m
Sterilizer Ctl Pressure (SCP) between 21.5 and 22.5 inHg at the end of this phase		22.0 inHg	PASS
2018-02-20 18:33	EVACUATION	CHAMBER3	23m
Sterilizer Ctl Pressure (SCP) between 1.5 and 2.5 inHg at the end of this phase		2.0 inHg	PASS
2018-02-20 18:56	RELEASE	CHAMBER3	23m
Sterilizer Ctl Pressure (SCP) between 24.7 and 25.8 inHg at the end of this phase		24.8 inHg	PASS
2018-02-20 19:19	CYCLE COMPLETE	CHAMBER3	8m
Sterilant Usage Total (SUT) at least 0.1b 5m before the start of this phase		56 lb	PASS
2018-02-20 19:27	TRANSFER TO AERATION	WORK/SL	14m
2018-02-20 19:40	AERATION	AERATION1	1d27m
duration between 1d and 3d		1d27m	PASS
cambi 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		AERATION3	INFO
- Aeration Temperatures (ATSC)		95 - 110 °F	INFO
- Aeration Temperatures (ATSM)		95 - 109 °F	INFO
- Aeration Circulation (AC1)		98 - 100	INFO
- minimum 1d in spec		1d14m	PASS
- maximum 30m out of spec (consecutive)		12m	PASS
Aeration Temperatures (ATSC) at most 120 °F		95 - 110 °F	PASS
Aeration Temperatures (ATSM) at most 120 °F		95 - 109 °F	PASS
2018-02-21 20:07	TRANSFER TO WAREHOUSE	PROC	12m
2018-02-21 20:20	REVIEW	PROC	4m
8 HR Hold (Nov - Apr.) (YES)		YES	PASS
Proc. Room RH Specs. Met (YES)		YES	PASS
Proc. Room Temp. Specs. Met (YES)		YES	PASS
Aeration Temperature Specs Met (YES)		YES	PASS
Remove Btl's Post Chamber (19 EA)		19	PASS
Place Btl'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.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 21 of 36

5725 W. Harold Gatty Rd.

Salt Lake City, UT 84116

9FEB'18 22:16

~~18FEB'18 22:30~~
13FEB'18

Inspection Satisfactory By: 03

Routine ☒ Validation / R & D ☐

Work Order:	2145452	Sales Order:	188 4247
(ABOVE FOR STERIGENICS USE ONLY)		(ABOVE FOR STERIGENICS USE ONLY)	
Customer Name:	Megadyne	Cycle #:	115
Address:	11506 South State Street	Customer Load #:	29660 29960
City:	Draper	Billing PO #:	29660 29960
State:	UT	Zip:	84020
"Shipping Instructions & Method Below"			

Technical Contact #:	T. Kessinger(801)553-2810
Logistics Contact #:	T. Kessinger(801)553-2810
Estimated Arrival Date:	Click here
EO Stat Request:	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
EO Stat Form Attached:	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

Ship to Name:	Megadyne
Address:	11506 South State Street
City:	Draper
State:	UT
Zip:	84020
Carrier:	Will Call
Account #	N/A
Ship. Method: Megadyne to pick own product	

PRODUCT IDENTIFICATION			
Number of Pallets:	4	Number of Cartons:	462
Number of BI's / PCID's:	19/1	Number of Positive Control BI's:	N/A
Lab Submission form attached:	YES NO		
LAL Samples:	YES NO 1	Number of LAL Samples to be removed:	N/A

Note: Product Identification may be listed below or an attached Packing List.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 22 of 36

Product ID	# Cartons	Product ID	# Cartons
SEE ATTACHED			

HANDLING / SPECIAL INSTRUCTIONS			
Please use this E-Mail address esterilization@megadyne.com for results.			

Customer Authorization Signature Required for Processing:		Date:	2-9-18
---	---	-------	--------

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 23 of 36

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Document: OPER-FRM-016 Rev: 001 Effective: 12 Apr 2013 12:00 AM

EO STERILIZATION

PART #	LOT #	STERILE QTY.	# OF BOXES	DATE OUT
0012M	180672	18012	69	2/9/18
0012AM	180673	9240	35	
0012AM	180729	9540	37	
0014AM	180810	8388	64	
0014M	180845	12,936	98	
0012M	180853	18,960	72	
0014MD	180791	480	2	
0036	180765	1500	30	
ENG TEST	~ ~ ~	~ ~ ~	6	
DAMAGE	~ ~ ~	~ ~ ~	49	

PREPARERS SIGNATURE: [Signature] DATE: 2-9-18
P/O#: 29660 of 2/2/18 29960, 29961
COMMENTS: # pallets = 4
BOXES = 462

REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	00-134-D1	Initial Release	2000-09-21

Printed on: 22 Jan 2018, 07:56:46 am; Printed by: EMCKENNA.

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 24 of 36

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NELSON
LABORATORIES

Nelson Laboratories, LLC | Details | Matters




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 1882
Preparation Date:	18 Jan 2018
BI Manufacturer's Information:	STERIS
	Part #NA005, Lot #2837
	Exp. 10 Apr 2019
BI Type:	Spore Strip
BI Manufacturer's Spore Population:	3.6×10^8 CFU/BI
NL Verified Population:	3.6×10^8 CFU/BI
Organism:	<i>Bacillus atrophaeus</i>

Tori Dieffenbacher electronically approved

Released by _____

Tori Dieffenbacher

22 Jan 2018 13:37

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 evidence 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. • 8280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.

Rev. 1.4.3

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 25 of 36

300654

CRM44151 Rcvd: 27 Nov 2017
Ambient Use By: 10 Apr 2019

BO 1862

STERIS

Opened: _____

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

CATALOG NUMBER: NA005 PRODUCT NAME: Spordex Strip
PRODUCT LOT NUMBER: C17023 SUBASSEMBLY LOT NUMBER: 2837
EXPIRATION DATE: April 10, 2019

Bacillus atrophaeus NRRL B4418:

Mean Population Recovery* (CFU): 3.6×10^6	Survival Time (Min.): 12.4
D ₉₀ Value** (Min.***): 2.7	Kill Time (Min.): 28.5
D ₉₉ Value** (Min.***): 1.6	Survival Time (Min.): 7.3
	Kill Time (Min.): 16.8

* 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 Thompson Date: 11/12/17
Reviewed By: Theresa Gifford Date: 11/17/17

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 Indicator 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 of other tortious conduct of STERIS.

PC800035 Revision Level: AN ECN# 76462
Effectivity Date: 09/22/2017

Page 1 of 1

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 26 of 36



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

Biological Indicator (BI) Sterility Test Final Report

Study Number: 1024509-S01
Test Article: Sterigenics Run #2145452
Purchase Order: 29661
Study Received Date: 22 Feb 2018
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	2837	10 Apr 2019	<i>Bacillus atrophaeus</i>	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



Derek L. Miller electronically approved

Study Director

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Derek L. Miller

01 Mar 2018 10:17 AM

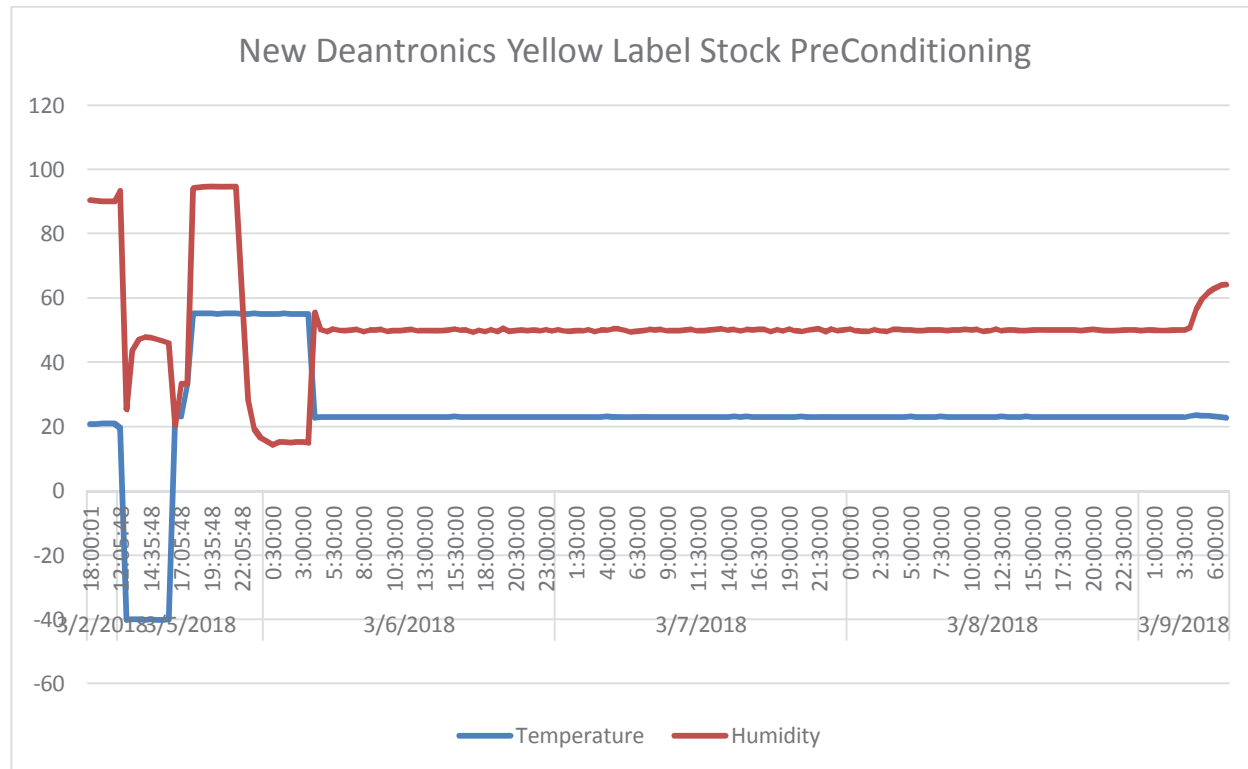
Study Completion Date and Time

Page 1 of 1

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 27 of 36

10. APPENDIX II – PRECONDITIONING



Date	Time	Air Temp	Humidity
3/2/2018	18:00:01	20.7	90.4
	18:30:01	20.8	90.3
	19:00:01	20.9	90.1
	19:30:01	20.9	90
	20:00:01	21	90
3/5/2018	12:05:48	19.6	93.4
	12:35:48	-40.2	25.3
	13:05:48	-40	43.9
	13:35:48	-40	47.3
	14:05:48	-40.1	47.8
	14:35:48	-40	47.6
	15:05:48	-40.1	47.2
	15:35:48	-40.1	46.6
	16:05:48	-40	46
	16:35:48	23.2	20.3

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 28 of 36

	17:05:48	23.1	33.2
	17:35:48	33.5	33.2
	18:05:48	55.2	94.2
	18:35:48	55.1	94.4
	19:05:48	55.1	94.6
	19:35:48	55.1	94.7
	20:05:48	55	94.6
	20:35:48	55.1	94.6
	21:05:48	55.1	94.7
	21:35:48	55.1	94.7
	22:05:48	55	62.9
	22:35:48	55	28.3
	23:05:48	55.1	19.4
	23:35:48	55	16.6
3/6/2018	0:00:00	54.9	15.5
	0:30:00	54.9	14.4
	1:00:00	54.9	15.1
	1:30:00	55.1	15.1
	2:00:00	55	14.9
	2:30:00	55	15.1
	3:00:00	55	15.1
	3:30:00	55	15
	4:00:00	22.8	55.6
	4:30:00	22.9	50.3
	5:00:00	23	49.7
	5:30:00	23	50.4
	6:00:00	23	50.1
	6:30:00	23	49.8
	7:00:00	23	50.1
	7:30:00	23	50.3
	8:00:00	22.9	49.6
	8:30:00	23	50.1
	9:00:00	23	50.1
	9:30:00	23	50.2
	10:00:00	23	49.7
	10:30:00	23	49.8
	11:00:00	23	49.9
	11:30:00	23	50

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 29 of 36

	12:00:00	23	50.3
	12:30:00	23	49.9
	13:00:00	23	49.8
	13:30:00	23	49.8
	14:00:00	23	49.8
	14:30:00	23	49.8
	15:00:00	23	50.1
	15:30:00	23.1	50.4
	16:00:00	23	50.1
	16:30:00	23	50.1
	17:00:00	23	49.5
	17:30:00	23	50
	18:00:00	23	49.7
	18:30:00	23	50.3
	19:00:00	23	49.7
	19:30:00	23	50.6
	20:00:00	23	49.6
	20:30:00	23	49.8
	21:00:00	23	50.1
	21:30:00	22.9	49.8
	22:00:00	23	50.1
	22:30:00	23	49.8
	23:00:00	23	50.2
	23:30:00	23	49.9
3/7/2018	0:00:00	23	50.3
	0:30:00	23	49.9
	1:00:00	23	49.7
	1:30:00	23	49.8
	2:00:00	23	49.9
	2:30:00	23	50.3
	3:00:00	23	49.6
	3:30:00	23	50.1
	4:00:00	23.1	50
	4:30:00	23	50.4
	5:00:00	23	50.4
	5:30:00	23	50
	6:00:00	23	49.5
	6:30:00	23	49.6

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 30 of 36

	7:00:00	23	49.9
	7:30:00	23	50.3
	8:00:00	23	50.1
	8:30:00	23	50.3
	9:00:00	23	49.8
	9:30:00	23	49.8
	10:00:00	23	49.8
	10:30:00	23	50.1
	11:00:00	23	50.3
	11:30:00	23	49.8
	12:00:00	23	49.8
	12:30:00	23	50
	13:00:00	23	50.3
	13:30:00	23	50.5
	14:00:00	22.9	50
	14:30:00	23.1	50.2
	15:00:00	23	49.9
	15:30:00	23.1	50.2
	16:00:00	23	50.1
	16:30:00	23	50.2
	17:00:00	23	50.3
	17:30:00	23	49.7
	18:00:00	23	50.2
	18:30:00	23	49.8
	19:00:00	23	50.4
	19:30:00	23	49.8
	20:00:00	23.1	49.7
	20:30:00	23	50
	21:00:00	23	50.2
	21:30:00	23	50.5
	22:00:00	23	49.7
	22:30:00	23	50.4
	23:00:00	23	49.9
	23:30:00	23	50.1
3/8/2018	0:00:00	23	50.4
	0:30:00	23	49.8
	1:00:00	23	49.6
	1:30:00	23	49.6

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 31 of 36

	2:00:00	23	50.3
	2:30:00	23	49.8
	3:00:00	23	49.7
	3:30:00	23	50.2
	4:00:00	23	50.3
	4:30:00	23	50
	5:00:00	23.1	50.1
	5:30:00	23	49.9
	6:00:00	23	49.8
	6:30:00	23	50
	7:00:00	23	50
	7:30:00	23.1	50
	8:00:00	23	49.9
	8:30:00	23	50
	9:00:00	23	50.1
	9:30:00	23	50.2
	10:00:00	23	50
	10:30:00	23	50.3
	11:00:00	23	49.7
	11:30:00	23	49.9
	12:00:00	23	50.4
	12:30:00	23.1	49.8
	13:00:00	23	50.1
	13:30:00	23	50.1
	14:00:00	23	49.8
	14:30:00	23.1	49.8
	15:00:00	23	50
	15:30:00	22.9	50
	16:00:00	23	50
	16:30:00	23	50
	17:00:00	23	50.1
	17:30:00	23	50
	18:00:00	23	50
	18:30:00	23	50.1
	19:00:00	23	49.9
	19:30:00	23	50
	20:00:00	23	50.2
	20:30:00	23	50

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 32 of 36

	21:00:00	23	49.9
	21:30:00	23	49.8
	22:00:00	23	49.9
	22:30:00	23	50
	23:00:00	23	50
	23:30:00	23	50.1
3/9/2018	0:00:00	23	49.8
	0:30:00	23	50
	1:00:00	22.9	50
	1:30:00	23	49.9
	2:00:00	23	49.8
	2:30:00	23	50.1
	3:00:00	23	50
	3:30:00	23	50.1
	4:00:00	23.3	50.9
	4:30:00	23.5	56.6
	5:00:00	23.4	59.8
	5:30:00	23.3	61.7
	6:00:00	23.1	62.9
	6:30:00	22.9	63.9
	7:00:00	22.8	64.1

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 33 of 36

11. APPENDIX III – SHIP TESTING

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Document: ENG-PRT-465 Rev: 001 Effective: 27 Feb 2018

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number ENG-PRT-465
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 10 of 12

APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: 3-2-2018 Chamber Number: 01268
Completion Date: 3-9-2018 Last Calibration: 5-23-2017
Signature/Date: Paul Valpreda Calibration due: 5-31-2018
3-12-2018

Drop Test:

Catalog 254X76MM Weight 3.5 lbs. Drop Height: 15"

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 3-12-2018
2	Edge	Edge 5-3	PV 3-12-2018
3	Edge	Edge 6-3	PV 3-12-2018
4	Corner	Corner 2-3-5	PV 3-12-2018
5	Corner	Corner 4-3-6	PV 3-12-2018
6	Bottom	Face 3	PV 3-12-2018

Comments: All six identical boxes passed. - PV

Signature: Paul Valpreda Date: 3-12-2018

Compression Test:

Catalog 254X76MM Pounds Force 210

Comments: All six identical boxes passed. - PV

Signature: Paul Valpreda Date: 3-12-2018

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 34 of 36

The user must ensure that they are using the correct/current revision of this document.
Document: ENG-PRT-465 Rev: 001 Effective: 27 Feb 2018

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number ENG-PRT-465
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 11 of 12

Appendix I Continued Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials PV High frequency 10 minutes, Initials PV

Completion Date: 3-12-2018

Signature: Paul Valpreda Date: 3-12-2018

Second Drop Test:

Catalog 254X76MM Weight 3.5 lbs. Drop Height: 15" + 30"

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 3-12-2018
2	Face	Face 4	PV 3-12-2018
3	Face	Face 6	PV 3-12-2018
4	Corner	Corner 2-1-5	PV 3-12-2018
5	Edge	Edge 2-1	PV 3-12-2018
6	Bottom	Face 3, Increase height to 30 inches.	PV 3-12-2018

Comments: All six identical boxes passed. - PV

Signature: Paul Valpreda Date: 3-12-2018

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 35 of 36

12. APPENDIX IV – LABEL CLARITY AND LEGIBILITY

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Document: ENG-PRT-465 Rev: 001 Effective: 27 Feb 2018

Megadyne Medical Products, Inc.	TEST PROTOCOL	<u>Document Number</u> ENG-PRT-465
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 12 of 12

Appendix II Label Clarity and Legibility Log Sheet

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

Catalog # ND-L100700	Pass	Fail
Clarity/Legibility	18 labels passed.	Ø

Comments: All 18 of the tested labels passed the Clarity and Legibility test. - PV

Paul Valpreda
Inspected by:

3-12-18
Date completed

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Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-581
	New Deantronics Yellow Label Stock EO Qualification	Revision: 001
		Page 36 of 36

13. APPENDIX V – LABEL CERTIFICATE OF COMPLIANCE



Taiwan
新典電通股份有限公司
New Deantronics Taiwan, Ltd.
12F, No.51, Sec.4,
Chong Yang Rd., Tu Cheng Dist.,
New Taipei City 20675,
Taiwan R.O.C.
Tel: +886 2 2266-1726
Fax: +886 2 2266-3600

USA
New Deantronics Ltd.
1090 North California Blvd.
Suite 1040
Walnut Creek, CA 94596
Tel: +1 (925) 260-6588
Fax: +1 (925) 260-1786



Certificate of Compliance

Customer Name:	MEGADYNE MEDICAL PRODUCTS, INC.
Invoice Number :	N/A
P. O. Number:	N/A
Customer P/N:	3151074-01
Drawing Number:	3151074-01 Rev.001
New Deantronics P/N:	L100700
Lot Number:	17102401
Quantity:	100 Pieces
Carton Number:	#1 ~ #1 (1 Carton)

Signed: *D. Y. Chen*

Printed Name: Da-Yu Chen

Title: Q.A. Director

Date: 10-24-2017

Materials

Plain Label

L100700, Heat transfer art paper

Mat'l Lot#

17101101