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	Shipping Test - Zip Pencil	<b>1150720-01</b>
	<b>MASTER DOCUMENT</b>	<b>Revision: A</b>
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*Mark Glassett 27 Mar 2014* *Darcy Greep 27 Mar 2014*  
Engineering Verification: D.C. Verification:

Authored By: Mark Glassett and Darcy Greep

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## 1. ABSTRACT

Zip Pencil 2525-10 samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes were subjected to the shipping test protocol 1150720-10 to show compliance to ISO 11607-1 after performance testing per ASTM D4169-05. The 2525-10 Zip Pencil shipping boxes and labels successfully passed the acceptance criteria outlined in the test protocol.

Zip Pencil 2525-15 samples subjected to the same testing as the 2525-10 above also met the requirements of the protocol and ISO 11607, however, processing issues with the manufacturer resulted in seals that were not complete; i.e. hot-tack release resulting in reduction of seal width or incomplete seals. No samples failed at the seal as a result of aging and test conditioning, and it is fully expected that with an improved process at the manufacturer, all seals will be complete. After process adjustments are made at the manufacturer, a second round of testing will be performed to validate that the process is in control and that fully formed seals without hot-tack issues are consistently created.

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## 2. OBJECTIVE

The objective of this test report is to document the ship testing that was done on the Zip Pencil catalog items 2525-10 and 2525-15 after accelerated aging to simulate three years expiration life and exposure to transport and storage conditions, to demonstrate conformance with ISO 11607-1:2006.

## 3. RESULTS

### 3.1. Accelerated Aging

Zip Pencils for testing were subjected to accelerated aging to simulate 3 years of shelf life. The samples that were exposed to this aging are as follows:

Catalog Number	Lot Number	Quantity
2525-10	S130230	54
2525-10	S130227	50
2525-15	S130231	20
2525-15	S130228	20

Documentation for aging is shown in Appendix IA. The documentation for the above lots is also in Appendix IA. The protocol references literature from the package material manufacturers stating that the materials meet ISO 11607 for aerosol challenge. This documentation is attached in Appendix VI.

### 3.2. Transport and Storage Cycle and Pre-Conditioning.

All of the above Zip Pencil samples for testing were subjected to the transport and storage cycle required by the protocol. This cycle includes temperatures from -40°C to 70°C and humidity's from 15% to 95%. The graph showing this cycle is in Appendix IA. Immediately following the transport and storage cycle the samples were pre-conditioned per ASTM D4169-05. The pre-conditioning parameters were to 23°C and 50% RH for a minimum of 72 hours. The environmental chamber was manually set to this temperature and humidity and the product was held at these conditions for 72 hours.

### 3.3. Shipping Test

The shipping test was performed by the Lab Technician. None of the boxes broke open during the test. There were minor indentations on the corners and edges of the boxes which is typical and acceptable per the protocol. This testing is documented on the log sheet in Appendix I.

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### 3.4. Print and Lot Number Clear and Legible

One case of each 2525-10 and 2525-15 were inspected per the protocol. The package print was clear and legible and passed the protocol acceptance criteria. The Lot numbers were correct and were clear and legible and passed the protocol acceptance criteria. This testing is documented on the log sheet in Appendix II.

### 3.5. Bubble Leak Test

The bubble leak test was performed on two boxes each of 2525-10 and 2525-15. The 2525-10 (10 foot) passed the bubble leak test criteria of the protocol. The data is shown in appendix III.

The 2525-15 (15 foot) had three packages that failed the bubble leak test. Review of each of these seals revealed a hot-tack release condition, with visible verification that the seal had been made initially, then abruptly pulled apart before the sealant layer could solidify. No further seal failure or separation was evident outside the area of this condition in each case. The supplier is making process adjustments and this test will be repeated for the 2525-15 product. The data is shown in appendix III.

### 3.6. Burst Test

The package burst test was performed on 11 each of 2525-10 and 2525-15. The minimum burst for the protocol was set at 19 in. H<sub>2</sub>O based on preliminary data provided by the manufacturer.

Of the 11 samples of 2525-10 there was one sample slightly below the limit at 18.6 in. H<sub>2</sub>O. This sample had previously passed the bubble leak test which indicates that the sample was fully sealed. The burst test is an in-process test to insure that seals are consistent. This burst test was performed after aging, temperature cycling and ship testing. These aging and cycling processes in conjunction with Gamma exposure may have detrimental effects on the package materials and could lead to lower burst values than when packages are fresh off the production line. Since the one package that measured lower than 19 in. H<sub>2</sub>O passed the bubble leak test and was only slightly below the production limit of 19 in. H<sub>2</sub>O, it is not considered a failure. Additional burst testing of non-aged product was performed. This product passed the minimum requirement of 19 in H<sub>2</sub>O in all cases. The data is shown in appendix IIIA.

Of the 11 samples of 2525-15 there were two samples significantly below 19 in. H<sub>2</sub>O. These samples were measured at 13.5 and 13.7 in. H<sub>2</sub>O. Further visual inspection of these seals revealed hot-tack reduction in seal width which would account for a reduction in burst test values. While these seals did not pass the minimum criteria for burst value, they did adequately protect the product from contamination through actual shipping from

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the manufacturer to Megadyne, as well as through all the aging, environmental conditioning, and ship test exposure conditions. This shows that the seals on these packages were adequate in their protective value for the product.

### 3.7. Minimum Seal Width

The aged packages used for the protocol did not meet the minimum requirements for minimum seal width for either catalog number. The non-aged samples manufactured at a later time met the requirements. Seal width data is shown in Appendix IV.

The minimum measured seal width for the 2525-10 product ranged from .12" to .38". However all of the packages passed bubble test indicating that they were sealed after shipping from the manufacturer, accelerated aging, environmental conditioning, and ship testing, and provided adequate protective value for the product. Visual inspection of the packages with low seal width showed that the narrow seal areas were initially sealed and experienced hot-tack release due to uncontrolled process conditions at the packaging machine. After more process development at the manufacturer, additional non-aged product, lot S130410, manufactured at a later time had minimum seal widths that ranged from .33 to .41 and meet the protocol requirement. This product was temperature cycled and ship tested but not aged and also passed bubble leak test. The low seal widths of the aged samples combined with the passing bubble leak test indicates that the product package is very robust even when the seals are not at their full widths. Also, evidence shows that the low seal widths were not caused by aging or ship testing. Therefore the protocol requirement for package seal width are accepted based on the non-aged samples.

### 3.8. Electrode Cap and Electrode Damage

One case of each 2525-10 and 2525-15 were inspected per the protocol. The cap was in place on the electrode on all of the samples and passed the protocol acceptance criteria. The electrodes were not damaged on any of the samples and passed the protocol acceptance criteria. The data is shown in appendix V.

## 4. DISCUSSION

The samples used for the ship testing are shown in the table below:

Catalog Number	Lot Number	Quantity
2525-10	S130230	20
2525-10	S130227	20
2525-15	S130231	20
2525-15	S130228	20

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#### 4.1. Shipping Test

Two cases of each 2525-10 and 2525-15 were subjected to the shipping test. The testing followed protocol 11560720-10 and consisted of pre-conditioning, drop test, compression test, vibration and a second drop test. The shipping test was completed with all four boxes meeting the acceptance criteria.

#### 4.2. Print and Lot Number Clear and Legible

The print and lot number inspections were performed by QA Inspectors. One case of each 2525-10 and 2525-15 were inspected per the protocol. The package print was clear and legible and passed the protocol acceptance criteria. The Lot numbers were correct and were clear and legible and passed the protocol acceptance criteria.

#### 4.3. Bubble Leak Test

The bubble leak test was performed per the requirements of the protocol and ASTM F2096 on two boxes each of 2525-10 and 2525-15. There are 20 pouches in each box for a total of 40 tests for each catalog number. All samples in the 2525-10 (10 foot) group passed the bubble leak test criteria of the protocol. The data is shown in appendix III.

The 2525-15 (15 foot) had three packages that failed the bubble leak test. One failure was in the box from lot S130228 and two failures were in the box from lot S130231. Two of the failures were in the right corner adjacent to the Chevron and the other one was at the center of the chevron. These failures are attributed to a processing condition on the manufacturer's equipment that resulted in a hot-tack release condition of the seal. The supplier is making process adjustments and this test will be repeated for the 2525-15 product. The data is shown in appendix III.

#### 4.4. Minimum Seal Width

The nominal seal width is designed to be .37" wide and the minimum for the protocol was set at .30". The aged packages used for the protocol did not meet the minimum requirements for either catalog number, again to a hot-tack release condition. Non-aged samples manufactured at a later time did meet the requirements. Seal width data is shown in Appendix IV.

The minimum seal width for the 2525-10 product ranged from .12" to .38". However all of the packages passed bubble test indicating that they were sealed after aging, temperature cycling and ship testing. Visual inspection of the packages with low seal width showed that the narrow seal areas were sealed initially, but experienced hot-tack separation before the sealant layer cooled, which is a result of a process defect at the

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packaging machine. Additional product, lot S130410, manufactured at a later time had minimum seal widths that ranged from .33 to .41. This product was temperature cycled and ship tested but not aged and also passed bubble leak testing. The low seal widths of the aged samples combined with the passing bubble test indicates that the product package is very robust even when the seals are not at their full width.

The aged samples were manufactured early in the design process to help get a head start on the validation process. They were not originally intended for package validation but plans changed and they were used for package validation. The improvement in the package seal demonstrated by the non-aged samples shows that the package development has progressed and that seal width requirements are being met on the current packages. This improvement, in connection with no seal failures based on actual test exposure conditions, allows the protocol requirement for package seal width to be accepted.

#### 4.5. Electrode Cap and Electrode Damage

The electrode cap and electrode damage inspections were performed by QA Inspectors. One case of each 2525-10 and 2525-15 were inspected per the protocol. The cap was in place on the electrode on all of the samples and passed the protocol acceptance criteria. The electrodes were not damaged on any of the samples and passed the protocol acceptance criteria. The data is shown in appendix V.

### 5. CONCLUSIONS

This testing demonstrates that the Zip Pencil 2525-10 samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes meet the requirements of ISO 11607-1 after performance testing per ASTM D4169-05. The testing shows that some in-process requirements were not met on the aged product but these requirements were met after process improvements as demonstrated on the non-aged product.

This testing demonstrates that the Zip Pencil 2525-15 samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes meet the requirements of ISO 11607-1 after performance testing per ASTM D4169-05. Failures observed during testing were not associated with test exposure or test conditions, but were based on processing issues at the manufacturer. With process improvements being made, testing on this product packaging configuration will be repeated.

### 6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Zip Pencil to ISO 11607-1 after performance testing per ASTM D4169-05 and three year accelerated aging to support the three year expiration life. This accelerated age test will support the three year

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expiration life of the product for market introduction. Real time age samples will be put aside for testing per Megadyne Protocol 1150309-10.

The testing also establishes shipping and storage conditions for labeling per IEC 60601-1:2005 clause 7.2.17. The shipping box labels of the products will show the international symbols for shipping and storage with temperatures of 5°C to 50°C and relative humidity of 15% to 95%. The IFU will include the note “Normal storage conditions are assumed. Brief excursion to temperature/humidity extremes is permitted”.

## 7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-040-01	Initial Release	2014 MAR 27

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**APPENDIX IA**  
See attached data

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**MASTER DOCUMENT**  
**Accelerated Aging In Process**

2014 MAR 27

Product: 2525-10 and 2525-15 Zip Pencil  
Lot Numbers S130227, S130228, S130230, S130231,

Temperature 55°  
Relative Humidity Ambient

Required Time 15 weeks 6 days  
(111 days)

Thermotron ID Number 01095

Last Calibration Date 3-28-2013

Calibration Due Date 3-31-2014

Start	Time	Initials	Stop	Time	Total	Initials
10 Oct 2013	14:00	mg PV	30 Jan 2014	14:00	111 days	mg PV

If this aging needs to be interrupted for any reason,  
contact Mark Glassett at ext. 845



2014 MAR 27

## MASTER DOCUMENT

NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
=ISO 13485:2003=

### Certificate of Compliance

Taiwan  
大塊企業股份有限公司  
New Deantronics Taiwan, Ltd.  
新北市土城區中央路4段51號12樓  
12F., No.51, Sec. 4,  
Chong Yang Rd, Tu Cheng Dist,  
New Taipei City 23675,  
Taiwan R.O.C.  
Tel: +886 2 2268-1726  
Fax +886 2 2268-3800

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** 20131001-MD  
**P. O. Number:** N/A  
**Customer P/N:** 2525-15(w/Global Med Tube)  
**Drawing Number:** X2525-15 Rev.02  
**New Deantronics P/N:** N/A (ZIP Pen, 15 Ft w/Global Med Tube)  
**Lot Number:** S130231  
**Expiration Date:** N/A  
**Quantity:** 20 Pieces  
**Carton Number:** #1 ~#1 (1 Carton)  
**Signed:**   
**Printed Name:** Da-Yu Chen  
**Title:** Q.A. Director

Date: 10-01-2013

#### USA

#### Note: T0 Sample.

New Deantronics Ltd.  
1990 North California Blvd.  
Suite 1040  
Walnut Creek, CA 94596  
Tel: +1 (925) 280-8388  
Fax +1 (925) 280-1788

Materials	ND Mat'l Lot#	Megadyne Lot#
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	120706
Plug material	F505100, TOP, ABS PA707 F505200, Bottom, ABS PA707	130917 130917
Terminal	T101701 Brass	111219
Overmold	R900801, TPR R300600, LDPE	120502 130917
Swivel, male	F916600, HDPE	130905
Swivel, Female	F917000, HDPE	130905
Connector	F916800, HDPE	130919
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	130904
Button	F302500, NYLON 66	130913
Tape	A100401, PTFE	130722
PCB	H201603, PCB FR-4	130710
Dome	M100600, 6mm 2 ROUND W/DMPL & FEET Printed on: 21 Jan 2020, 09:00:19 pm, Printed by: 	130820



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= ISO 13485:2003 =

2014 MAR 27

	Pen Body	F105400, ABS+TPR	130917
	Nozzle	F916300, PC	130913
Taiwan	Collet Holder	F918100, PC	130913
大塊企業股份有限公司	Carriage	F916500, ABS	130917
New Deantronics Taiwan, Ltd.	Snap Swivel, Male	F916400, HDPE	130906
新北市土城區中央路4段51號12樓	Snap Swivel, Female	F918300, HDPE	130906
12F, No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist,	Tubing, Connector	F916700, HDPE	130906
New Taipei City 23675, Taiwan R.O.C.	Tubing, Convoluted	P305600, EVA 8"	130809
Tel: +886 2 2268-1726 Fax: +886 2 2268-3800	Tubing, Convoluted	P305700, EVA 56"	130809
USA	Holster	F916900, HDPE	130913
New Deantronics Ltd.	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	120816(20pcs) 21720
1990 North California Blvd. Suite 1040	Paper Band	A900300	130507
Walnut Creek, CA 94596 Tel: +1 (925) 280-8388 Fax: +1 (925) 280-1788	Tyvek	A000400	130819
	Nylon Film	Nylon	130903
	Glue	S400900, Loctite 4061	130913
	Ink	S102000, Green, PMS356C	121127
	IFU PN and REV	P/N3000185-01 Rev.A	130910



中國生化科技股份有限公司

CHINA BIOTECH CORPORATION

誠信正直，顧客感動，社會公道

TEL: 886-4-23597515 FAX: 886-4-23597080

台中市工業區33路10號

10, 33<sup>rd</sup> Road, Taichung Industrial Park,

Taichung, Taiwan R.O.C 407

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2014 MAR 27

DATE : 2013/10/1

照射證明書  
CERTIFICATE OF IRRADIATION

REVISED

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大瓏企業(股)公司  
NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2013/09/25

照射批號 IRRADIATION RUN NUMBER : NEW13604-N1

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
20	2525-15 (Prototypes, Not For Clinical Use)	S130231/R12017

總 數 20 支 數  
TOTAL PCS

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：

China Biotech Corporation certifies that the material listed above (has described by its manufacturer)  
received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 51.0 kGy ; 最 高 劑 量 54.1 kGy  
MINIMUM DOSAGE 51.0 kGy ; MAXIMUM DOSAGE 54.1 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量 MIN 50.0 kGy ; 最高劑量 MAX 60.0 kGy

PS:For Accelerated Aging Test

確 認 者: 江人和  
CERTIFIED BY  
品保部主管  
QUALITY ASSURANCE

# MASTER DOCUMENT

## Certificate of Compliance

2014 MAR 27

<b>Taiwan</b>  大塚企業股份有限公司 New Deantronics Taiwan, Ltd. 新北市土城區中央路4段51號12樓 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist, New Taipei City 23675, Taiwan R.O.C. Tel: +886 2 2268-1726 Fax: +886 2 2268-3800	<b>Customer Name:</b> MEGADYNE MEDICAL PRODUCTS, INC. <b>Invoice Number :</b> 20131001-MD <b>P. O. Number:</b> N/A <b>Customer P/N:</b> 2525-10 (w/Global Med Tube) <b>Drawing Number:</b> X2525-10 Rev.02 <b>New Deantronics P/N:</b> PB352SM1 (w/Global Med Tube) <b>Lot Number:</b> S130230 <b>Expiration Date:</b> N/A <b>Quantity:</b> 60 Pieces <b>Carton Number:</b> #1 ~#3 (3 Cartons) <b>Signed:</b> <i>D. Y. Chen</i> <b>Printed Name:</b> Da-Yu Chen <b>Title:</b> Q.A. Director
---	---

**Date:** 10-01-2013

**USA**

**Note: T0 Sample.**

New Deantronics Ltd.  
1990 North California Blvd.  
Suite 1040  
Walnut Creek, CA 94596  
Tel: +1 (925) 280-8388  
Fax: +1 (925) 280-1788

<u>Materials</u>	<u>ND</u>	<u>Megadyne</u>
<u>Mat'l Lot#</u>	<u>Lot#</u>	
Cable	C302600	120706
	Conductor : 7/0.16*3BC(26 AWG)	
	Bare copper	
	Insulation: PPE, one red, one blue & one white	
	Outer jacket: PVC, Gray	
Plug material	F505100, TOP, ABS PA707	130917
	F505200, Bottom, ABS PA707	130917
Terminal	T101701 Brass	111219
Overmold	R900801, TPR	120502
	R300600, LDPE	130917
Swivel, male	F916600, HDPE	130905
Swivel, Female	F917000, HDPE	130905
Connector	F916800, HDPE	130919
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	130904-130913
Button	F302500, NYLON 66	130913
Tape	A100401, PTFE	130722
PCB	H201603, PCB FR-4	130710
Dome	M100600, 6mm ROUND W/DIMPLE & FEET	130820

QR-002-2



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2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
= ISO 13485:2003 =

	Pen Body	F105400, ABS+TPR	130917
	Nozzle	F916300, PC	130913
Taiwan	Collet Holder	F918100, PC	130913
大塊企業股份有限公司	Carriage	F916500, ABS	130917
New Deantronics Taiwan, Ltd. 新北市土城區中央路4段51號12樓 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist., New Taipei City 23675, Taiwan R.O.C. Tel: +886 2 2268-1726 Fax: +886 2 2268-3800	Snap Swivel, Male	F916400, HDPE	130906
	Snap Swivel, Female	F918300, HDPE	130906
	Tubing, Connector	F916700, HDPE	130906
	Tubing, Convoluted	P305600, EVA 8"	130809
	Tubing, Convoluted	P305700, EVA 56"	130809
USA	Holster	F916900, HDPE	130913
New Deantronics Ltd. 1990 North California Blvd. Suite 1040 Walnut Creek, CA 94596 Tel: +1 (925) 280-8388 Fax: +1 (925) 280-1788	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	120816 (60pcs) 21720
	Paper Band	A900300	130507
	Tyvek	A000400	130819
	Nylon Film	Nylon	130903
	Glue	S400900, Loctite 4061	130913
	Ink	S102000, Green, PMS356C	121127
	IFU PN and REV	P/N3000185-01 Rev.A	130910

# MASTER DOCUMENT



中國生化科技股份有限公司

CHINA BIOTECH CORPORATION

誠信正直·極致感動·社會公道

TBL:886-4-23597515 FAX:886-4-23597080

台中市工業區33路10號

10, 33<sup>rd</sup> Road, Taichung Industrial Park,

Taichung, Taiwan R.O.C 407

2014 MAR 27

DATE : 2013/10/1

## 照射證明書 CERTIFICATE OF IRRADIATION

REVISED

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大瓏企業(股)公司

NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2013/09/25

照射批號 IRRADIATION RUN NUMBER : NEW13604-N4

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
60	2525-10(PB352SM1) (Prototypes, Not For Clinical Use)	S130230/R12017

總 數 60 支 PCS

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：

China Biotech Corporation certifies that the material listed above (has described by its manufacturer) received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 51.0 kGy ; 最 高 劑 量 54.1 kGy  
MINIMUM DOSAGE 51.0 kGy ; MAXIMUM DOSAGE 54.1 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量 MIN 50.0 kGy ; 最高劑量 MAX 60.0 kGy

PS:For Accelerated Aging Test

確 認 者: 鄒小玲  
CERTIFIED BY 鄒小玲  
品保部主管  
QUALITY ASSURANCE



*Aging Samples*  
**MASTER DOCUMENT**  
2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
=ISO 13485:2003=

**Certificate of Compliance**

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.

**Invoice Number :** 20131001-MD

**P. O. Number:** N/A

**Customer P/N:** 2525-15(w/Smooth Bor Tube)

**Drawing Number:** X2525-15 Rev.02

**New Deantronics P/N:** NA (ZIP Pen, 15 Ft w/Smooth Bor Tube)

**Lot Number:** S130228

**Expiration Date:** N/A

**Quantity:** 20 Pieces

**Carton Number:** #1 ~#1 (1 Carton)

**Signed:** *D. Y. Chen*

**Date:** 10-01-2013

**Printed Name:** Da-Yu Chen

**Title:** Q.A. Director

**Note: T0 Sample.**

**USA**

	<u>Materials</u>	<u>ND</u>	<u>Megadyne</u>
		<u>Mat'l Lot#</u>	<u>Lot#</u>
1990 North California Blvd. Suite 1040 Walnut Creek, CA. 94596 Tel +1 (925) 280-8388 Fax +1 (925) 280-1788	Cable Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	120706	
	Plug material F505100, TOP, ABS PA707 F505200, Bottom, ABS PA707	130917 130917	
	Terminal T101701 Brass	111219	
	Overmold R900801, TPR R300600, LDPE	120502 130917	
	Swivel, male F916600, HDPE	130905	
	Swivel, Female F917000, HDPE	130905	
	Connector F916800, HDPE	130919	
	Collet Terminal T202502, Phosphor Bronze contact plated nickel	130904-130913	
	Button F302500, NYLON 66	130913	
	Tape A100401, PTFE	130722	
	PCB H201603, PCB FR-4	130710	
	Dome M100600, 6mm ROUND W/DIMPLE & FEET	130820	



# MASTER DOCUMENT



2014 MAR 27

NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
= ISO 13485:2003 =

Taiwan	Pen Body	F105400, ABS+TPR	130917
大塚企業股份有限公司 New Deantronics Taiwan, Ltd. 新北市土城區中央路4段51號12樓 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist., New Taipei City 23675, Taiwan R.O.C. Tel: +886 2 2268-1726 Fax +886 2 2268-3800	Nozzle	F916300, PC	130913
	Collet Holder	F918100, PC	130913
	Carriage	F916500, ABS	130917
	Snap Swivel, Male	F916400, HDPE	130906
	Snap Swivel, Female	F918300, HDPE	130906
	Tubing, Connector	F916700, HDPE	130906
	Tubing, Convoluted	POE 8"	130809
	Tubing, Convoluted	POE 56"	130809
	Holster	F916900, HDPE	130913
USA	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	120816(20pcs) 21720
New Deantronics Ltd. 1990 North California Blvd. Suite 1040 Walnut Creek, CA. 94596 Tel: +1 (925) 280-8388 Fax +1 (925) 280-1788	Paper Band	A900300	130507
	Tyvek	A000400	130819
	Nylon Film	Nylon	130903
	Glue	S400900, Loctite 4061	130913
	Ink	S102000, Green, PMS356C	121127
	IFU PN and REV	P/N3000185-01 Rev.A	130910

## MASTER DOCUMENT



中國生化科技股份有限公司

CHINA BIOTECH CORPORATION

誠信正直·顧客為尊·社會公道

TEL: 886-4-23597515 FAX: 886-4-23597080

台中市工業區33路10號

10, 33<sup>rd</sup> Road, Taichung Industrial Park,

Taichung, Taiwan R.O.C 407

2014 MAR 27

DATE : 2013/10/1

照射證明書  
CERTIFICATE OF IRRADIATION

REVISED

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大瓏企業(股)公司  
NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2013/09/25

照射批號 IRRADIATION RUN NUMBER : NEW13604-N2

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
20	2525-15 (Prototypes, Not For Clinical Use)	S130228/R12017

總 數 20 支 PCS 數

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：

China Biotech Corporation certifies that the material listed above (has described by its manufacturer) received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 51.0 kGy ; 最 高 劑 量 54.1 kGy  
MINIMUM DOSAGE 51.0 kGy ; MAXIMUM DOSAGE 54.1 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量 MIN 50.0 kGy ; 最高劑量 MAX 60.0 kGy

PS:For Accelerated Aging Test

確 認 者: 江人傑  
CERTIFIED BY  
品保部主管  
QUALITY ASSURANCE



# Aging Samples MASTER DOCUMENT

2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
=ISO 13485:2003=

## Certificate of Compliance

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.

**Invoice Number :** 20131001-MD

**P. O. Number:** N/A

**Customer P/N:** 2525-10 (w/Smooth Bor Tube)

**Drawing Number:** X2525-10 Rev.02

**New Deantronics P/N:** PB352SM1 (w/Smooth Bor Tube)

**Lot Number:** S130227

**Expiration Date:** N/A

**Quantity:** 59 Pieces

**Carton Number:** #1 ~#3 (3 Cartons)

**Signed:** *D. Y. Chen*

**Date:** 10-01-2013

**Printed Name:** Da-Yu Chen

**Title:** Q.A. Director

**Taiwan**

大壩企業股份有限公司  
New Deantronics Taiwan, Ltd.  
新北市土城區中央路4段51號12樓  
12F., No.51, Sec. 4,  
Chong Yang Rd., Tu Cheng Dist.,  
New Taipei City 23675,  
Taiwan R.O.C.  
Tel: +886 2 2268-1726  
Fax +886 2 2268-3800

**Note: T0 Sample.**

New Deantronics Ltd.  
1990 North California Blvd.  
Suite 1040  
Walnut Creek, CA. 94596  
Tel: +1 (925) 280-8388  
Fax +1 (925) 280-1788

<u>Materials</u>	<u>ND</u>	<u>Megadyne</u>
	<u>Mat'l Lot#</u>	<u>Lot#</u>
Cable	120706	
Conductor : 7/0.16*3BC(26 AWG)		
Bare copper		
Insulation: PPE, one red, one blue & one white		
Outer jacket: PVC, Gray		
Plug material	130917	
F505100, TOP, ABS PA707	130917	
F505200, Bottom, ABS PA707		
Terminal	111219	
T101701 Brass		
Overmold	120502	
R900801, TPR	130917	
R300600, LDPE		
Swivel, male	130905	
F916600, HDPE		
Swivel, Female	130905	
F917000, HDPE		
Connector	130919	
F916800, HDPE		
Collet Terminal	130904-130913	
T202502, Phosphor Bronze contact plated nickel		
Button	130913	
F302500, NYLON 66		
Tape	130722	
A100401, PTFE		
PCB	130710	
H201603, PCB FR-4		
Dome	130820	
M100600, 6mm ROUND W/DIMPLE & FEET		
Printed on: 24 Jan 2020, 09:00:19 pm, Printed by: .		



2014 MAR 27

NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
= ISO 13485:2003 =

Taiwan	Pen Body	F105400, ABS+TPR	130917
	Nozzle	F916300, PC	130913
	Collet Holder	F918100, PC	130913
大塊企業股份有限公司 New Deantronics Taiwan, Ltd. 新北市土城區中央路4段51號12樓 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist, New Taipei City 23675, Taiwan R.O.C. Tel: +886 2 2268-1726 Fax: +886 2 2268-3800	Carriage	F916500, ABS	130917
	Snap Swivel, Male	F916400, HDPE	130906
	Snap Swivel, Female	F918300, HDPE	130906
	Tubing, Connector	F916700, HDPE	130906
	Tubing, Convoluted	POE 8"	130809
	Tubing, Convoluted	POE 56"	130809
USA	Holster	F916900, HDPE	130913
New Deantronics Ltd. 1990 North California Blvd. Suite 1040 Walnut Creek, CA 94596 Tel: +1 (925) 280-8388 Fax: +1 (925) 280-1788	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	120816 (59pcs) 21720
	Paper Band	A900300	130507
	Tyvek	A000400	130819
	Nylon Film	Nylon	130903
	Glue	S400900, Loctite 4061	130913
	Ink	S102000, Green, PMS356C	121127
	IFU PN and REV	P/N3000185-01 Rev.A	130910



# 中國生化科技股份有限公司 MASTER DOCUMENT

CHINA BIOTECH CORPORATION  
誠信正直，顧客感動，社會公道  
TEL:886-4-23597515 FAX:886-4-23597080  
台中市工業區33路10號  
10, 33<sup>rd</sup> Road, Taichung Industrial Park,  
Taichung, Taiwan R.O.C 407

2014 MAR 27

DATE : 2013/10/1

## 照射證明書 CERTIFICATE OF IRRADIATION

REVISED

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大璵企業(股)公司  
NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2013/09/25

照射批號 IRRADIATION RUN NUMBER : NEWI3604-N3

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
59	2525-10(PB352SM1) (Prototypes, Not For Clinical Use)	S130227/R12017

總 數 59 支 數  
TOTAL PCS

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：

China Biotech Corporation certifies that the material listed above (has described by its manufacturer) received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 51.0 kGy ; 最 高 劑 量 54.1 kGy  
MINIMUM DOSAGE 51.0 kGy ; MAXIMUM DOSAGE 54.1 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鎔 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量 MIN 50.0 kGy ; 最高劑量 MAX 60.0 kGy

PS:For Accelerated Aging Test

確 認 者: 劉文傑  
CERTIFIED BY  
品保部主管  
QUALITY ASSURANCE



# MASTER DOCUMENT

2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
=ISO 13485:2003=

## Certificate of Compliance

Taiwan

大成企業股份有限公司

New Deantronics Taiwan, Ltd.

新北市土城區中興路一段 51 號 12 樓

12F, No.51, Sec. 4,

Chong Yang Rd., Tu Cheng Dist.

New Taipei City 23675,

Taiwan R.O.C.

Tel: +886 2 2268-1728

Fax: +886 2 2268-3800

USA

New Deantronics Ltd.

1990 North California Blvd.

Suite 1040

Walnut Creek, CA 94566

Tel: +1 (925) 260-8388

Fax: +1 (925) 260-1788

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** MD-431/14  
**P. O. Number:** 23707  
**Customer P/N:** 2525-10 (w/Smooth Bor Tube)  
**Drawing Number:** X2525-10 Rev.02  
**New Deantronics P/N:** PB352SM1 (ZIP Pen, 10ft w/Smooth Bor Tube)  
**Lot Number:** S130409  
**Expiration Date:** N/A  
**Quantity:** 60 Pieces  
**Carton Number:** #1 ~#3 (3 Cartons)  
**Signed:** *D. Y. Chen*  
**Printed Name:** Da-Yu Chen  
**Title:** Q.A. Director

Date: 01-08-2014

Revised: 02-21-2014

**Note: Only for sample test not for clinical used.**

### Materials

		ND Mat'l Lot#	Megadyne Lot#
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	131014Z	
Plug material	F505100, TOP, ABS PA707 F505200, Bottom, ABS PA707	130917 130917	
Terminal	T101702 Brass, Plating Nickel.	131030	
PCB Overmold	R900801, TPR	130801	
Swivel, male	F916600, HDPE	S130301	
Swivel, Female	F917000, HDPE	S130301	
Connector Proximal	F916800, HDPE	131231	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	131211	
Button	F302500, NYLON 66	131217	
Tape	A100401, PTFE	131002	
PCB	H201603, PCB FR-4	130710	
Dome	M100600, 6mm ROUND W/DIMPLE & FEET	130820	

QR-002-2

**MASTER DOCUMENT**

2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
ISO 13485:2003

Taiwan	Pen Body	F105400, ABS+TPR	131217
大成企管股份有限公司 New Deantronics Taiwan, Ltd. 新北市土城區中興路4段51號12樓 12F., No.51, Sec.4, Chong Yang Rd, Tu Cheng Dist, New Taipei City 23675, Taiwan R.O.C. Tel: +886 2 2268-1726 Fax: +886 2 2268-3000	Nozzle	F916300, PC	131217
	Collet Holder	F918100, PC	131217
	Carriage	F916500, ABS	131217
	Snap Swivel, Male	F916400, HDPE	S130302
	Snap Swivel, Female	F918300, HDPE	S130302
	Tubing, Connector	F916700, HDPE	S130318
USA	Tubing, Convolved	POE 8.5"	130809
New Deantronics Ltd. 1990 North California Blvd. Suite 1040 Walnut Creek, CA 94596 Tel: +1 (925) 280-8388 Fax: +1 (925) 280-1788	Tubing, Convolved	POE 56"	130809
	Holster	F916900, HDPE	130913
	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	131205 (60pcs) 133630
	Paper Band	A900300	130507
	Tyvek	A000400	131031
	Nylon Film	A000500, Nylon	131028
	Glue	S400900, Loctite 4061	130913
	Ink	S102000, Green, PMS356C	121127
	IFU PN and REV	P/N3000185-01 Rev.A	130910

QR-002-2



# MASTER DOCUMENT

2014 MAR 27



NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
ISO 13485:2003

## Certificate of Compliance

Taiwan  
大連企業股份有限公司  
New Deantronics Taiwan, Ltd.  
新北市土城店中路3段4251號12樓  
12F., No.51, Sec. 4,  
Chong Yang Rd, Tu Cheng Dist.,  
New Taipei City 23675,  
Taiwan R.O.C.  
Tel: +886 2 2268-1726  
Fax: +886 2 2268-3800

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** MD-431/14  
**P. O. Number:** 23707  
**Customer P/N:** 2525-10 (w/Global Med Tube)  
**Drawing Number:** X2525-10 Rev.02  
**New Deantronics P/N:** PB352SM1 (ZIP PEN, 10ft w/Global Med Tube)  
**Lot Number:** S130410  
**Expiration Date:** N/A  
**Quantity:** 60 Pieces  
**Carton Number:** #1 ~#3 (3 Cartons)  
**Signed:** *D. Y. Chen* **Date:** 01-08-2014  
**Printed Name:** Da-Yu Chen **Revised:** 02-21-2014  
**Title:** Q.A. Director

USA  
New Deantronics Ltd.  
1930 North California Blvd.  
Suite 1040  
Walnut Creek, CA 94596  
Tel: +1 (925) 280-8388  
Fax: +1 (925) 280-1789

**Note: Only for sample test not for clinical used.**

Materials

		<u>ND</u> <u>Mat'l</u>	<u>Megadyne</u> <u>Lot#</u>
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	131014Z	
Plug material	F505100, TOP, ABS PA707 F505200, Bottom, ABS PA707	130917 130917	
Terminal	T101702, Brass Plating Nickel.	131030	
PCB Overmold	R900801, TPR	130801	
Swivel, male	F916600, HDPE	S130301	
Swivel, Female	F917000, HDPE	S130301	
Connector Proximal	F916800, LDPE	131231	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	131211	
Button	F302500, NYLON 66	131217	
Tape	A100401, PTFE	131002	
PCB	H201603, PCB FR-4	130710	
Dome	M100600, 6mm ROUND W/DIMPLE & FEET	130820	

QR-002-2



# MASTER DOCUMENT



2014 MAR 27

NEW DEANTRONICS TAIWAN, LTD. WITH  
QUALITY SYSTEM  
CERTIFIED BY DNV  
=ISO 13485:2003=

Taiwan

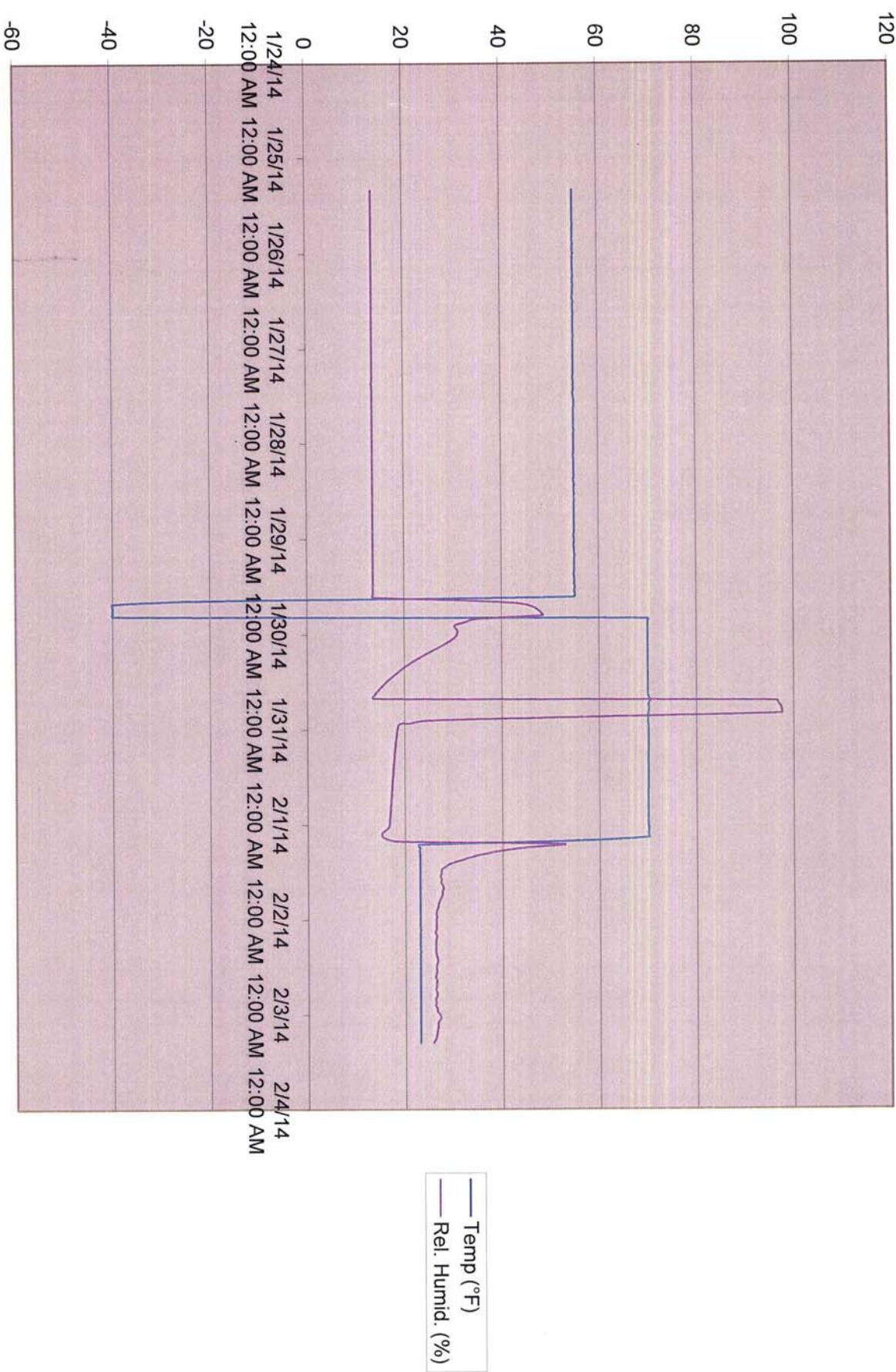
大成企管諮詢有限公司  
New Deantronics Taiwan, Ltd.  
新北市土城區中央路4段51號12樓  
12F., No.51, Sec. 4,  
Chong Yang Rd, Tu Cheng Dist.,  
New Taipei City 23675,  
Taiwan R.O.C.  
Tel +886 2 2268-1726  
Fax +886 2 2268-3800

Pen Body	F105400, ABS+TPR	131217
Nozzle	F916300, PC	131217
Collet Holder	F918100, PC	131217
Carriage	F916500, ABS	131217
Snap Swivel, Male	F916400, HDPE	S130302
Snap Swivel, Female	F918300, HDPE	S130302
Tubing, Connector	F916700, HDPE	S130318
-----		
USA		
New Deantronics Ltd. 1990 North California Blvd Suite 1040 Walnut Creek, CA 94596 Tel +1 (925) 280-6388 Fax +1 (925) 280-1788		
Tubing, Convolute	P305600, EVA 8"	130828
Tubing, Convolute	P305700, EVA 56"	130828
Holster	F916900, HDPE	130913
Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	131205 (60pcs) 133630
Paper Band	A900300	130507
Tyvek	A000400	131031
Nylon Film	A000500, Nylon	131028
Glue	S400900, Loctite 4061	130913
Ink	S102000, Green, PMS356C	121127
IFU PN and REV	P/N3000185-01 Rev.A	130910

QR-002-2

# MASTER DOCUMENT

2014 MAR 27



Megadyne Medical Products, Inc.	MASTER DOCUMENT TEST PROTOCOL	2014 MAR 27 Document Number X1150720-10
	Shipping Test – Zip Pencil	Revision: 02
		Effective Date:
		Page 17 of 22

### Appendix I Shipping Test Log Sheet

Preconditioning:

Start Date: Jan. 26, 2014 Chamber Number: 01095  
Completion Date: Feb. 4, 2014 Last Calibration: 3-28-2013  
Signature/Date: Paul Valpreda 2-4-2014 Calibration due: 3-31-2014

Drop Test:

Catalog 2525-10/15 Weight 13 lbs Drop Height: 15" and 30"  
Lot #'s S130230, S130227, S130231, S130228

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 2-4-2014
2	Edge	Edge 5-3	PV 2-4-2014
3	Edge	Edge 6-3	PV 2-4-2014
4	Corner	Corner 2-3-5	PV 2-4-2014
5	Corner	Corner 4-3-6	PV 2-4-2014
6	Bottom	Face 3	PV 2-4-2014

Comments: \_\_\_\_\_

Signature: Paul Valpreda Date: 2-4-2014

Compression Test:

Catalog 2525-10/15 Pounds Force 275

Comments: \_\_\_\_\_

Signature: Paul Valpreda Date: 2-4-2014

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MASTER DOCUMENT

Megadyne Medical Products, Inc.	TEST PROTOCOL	<u>Document Number</u> X1150720-10
	Shipping Test – Zip Pencil	<u>Revision:</u> 02
		<u>Effective Date:</u>
		<u>Page 18 of 22</u>

**Appendix I Continued**  
**Shipping Test Log Sheet**

Vibration:

Low Frequency, 40 minutes, Initials PV High frequency 10 minutes, Initials PVCompletion Date: 2-4-2014

Signature:

Paul ValpredaDate: 2-4-2014

Second Drop Test:

Catalog 2525-10/15 Weight 131bs ea. Drop Height: 15" and 30"

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 2-4-2014
2	Face	Face 4	PV 2-4-2014
3	Face	Face 6	PV 2-4-2014
4	Corner	Corner 2-1-5	PV 2-4-2014
5	Edge	Edge 2-1	PV 2-4-2014
6	Bottom	Face 3, Increase height to 30 inches.	PV 2-4-2014

Comments: \_\_\_\_\_

Signature:

Paul ValpredaDate: 2-4-2014

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2014 MAR 27

MASTER DOCUMENT		Document Number
Megadyne Medical Products, Inc.	TEST PROTOCOL	X1150720-10
		Revision: 02
	Shipping Test – Zip Pencil	Effective Date:
		Page 19 of 22

## Appendix II

### Print Legibility Log Sheet

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

Catalog # 2525-15	Pass	Fail
Pouch Print	20	
Lot Number Print S130231	20	

Comments: \_\_\_\_\_

Chitt Vongdara 2/5/14  
Inspected by: Date completed

Inspected by:

2/5/14  
Date completed

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		Effective Date:
		Page 19 of 22

**Appendix II**  
**Print Legibility Log Sheet**

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

Catalog #	Pass	Fail
Pouch Print	20	
Lot Number Print	20	

Comments: \_\_\_\_\_

\_\_\_\_\_  
Inspected by:

Chit Kongdara

2/5/14  
Date completed

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2014 MAR 27

Appendix III  
Bubble Leak Test

Bubble Leak Test Log Sheet			
BOX A1 - Catalog # 2525-10, LOT S130230			
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		

Bubble Leak Test Log Sheet			
BOX B1 - Catalog # 2525-10, LOT S130227			
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		

Bubble Leak Test Log Sheet			
BOX C1 - Catalog # 2525-15, LOT S130231			
Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9		X	Upper right corner
10	X		
11	X		
12	X		
13		X	Along chevron
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		

Bubble Leak Test Log Sheet			
BOX D1 - Catalog # 2525-15, LOT S130228			
Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4		X	Upper right corner
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		

Paul Valpreda  
OPERATOR NAME

2/5/2014  
DATE

Paul Valpreda  
OPERATOR SIGNATURE

2-26-2014  
DATE

<b>Megadyne Medical Products, Inc.</b>	<b>TEST REPORT</b>	<b>Document Number</b>
	<b>Shipping Test - Zip Pencil</b>	<b>1150720-01</b>
	<b>MASTER DOCUMENT</b>	<b>Revision: A</b>
		<b>Effective Date:</b> <b>2014 MAR 27</b>
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**APPENDIX IIIA**  
See attached data

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Megadyne Medical Products, Inc.	Inspection Form		Document Number <b>1030024-01</b>
	Revision: Y Effectivity Date: 2012-10-30 Page 1 of 4		
	Peel Pouch- Seal Burst Test		
	Lucy Richards 2012 OCT 30		

Tim Kessinger 2012 OCT 25  
D.C. Verification:  
Second Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
9130230	2535-10	210 μm Smoke Evaluation Pouch	2014-11-14	12

Unless otherwise specified, the sampling plan is C=0.

Burst / Creep Inspection method is specified by 1100016-10.

Specification, Burst Date: 21/11/14 Initials Burst Data, Pass/Fail – List Lane #'s for Multivac Only  
in. H<sub>2</sub>O

Time	Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3
10:10	✓	10:37	A1-14	22-1		
			A1-11	19.8		
			A1-19	21-1		
			A1-4	24.7		
			A1-3	20.2		
			A1-2	22.8		
			A1-1	21.8		
			A1-12	18.6		
			A1-13	21.3		
			A1-20	19.5		
			A1-10	19.4		
10:45	✓	A1-9	23.2			

**MASTER DOCUMENT**

2014 MAR 27

Megadyne Medical Products, Inc.	<b>Inspection Form</b>	<b>Document Number</b> <b>1030024-01</b>
<b>Revision: Y</b>		
<b>Effectivity Date:</b> <b>2012-10-30</b>		
<b>Page 1 of 4</b>		

Lucy Richards 2012 OCT 30

D.C. Verification:

Tim Kessinger 2012 OCT 25

Second Verification:

<b>Lot Number</b>	<b>Catalog Number</b>	<b>Description</b>	<b>Date Tested</b>	<b>Quantity Tested</b>
530410	2525-10	2.10 per Trauma Pouch	27/14	11

Unless otherwise specified, the sampling plan is C=0.

Burst / Creep Inspection method is specified by 1100016-10.

**Specification, Burst Date:** 21/14    **Initials**    **Burst Data, Pass/Fail – List Lane #'s for Multivac Only**

in. H<sub>2</sub>O

<b>Time</b>	<b>Lane #</b>	<b>pouch 1</b>	<b>Lane #</b>	<b>pouch 2</b>	<b>Lane #</b>	<b>pouch 3</b>
10.	10.	10:20.	12	11.5	10.3	
			E1-6	21.4.		
			E1-7	21.1		
			E1-8	20.0		
			E1-9	19.2		
			E1-3	21.8		
			E1-10	21.7		
			E1-2	21.6		
			E1-9	22.6		
			E1-11	22.1		
10:32	E1-1	23.2	E1-1	23.2		

# MASTER DOCUMENT

2014 MAR 27

Megadyne Medical Products, Inc.	Inspection Form		Document Number <b>1030024-01</b>
	Peel Pouch- Seal Burst Test		
	Revision: Y		
	Effectivity Date: 2012-10-30		
	Page 1 of 4		

Lucy Richards 2012 OCT 30  
D.C. Verification:

Tim Kessinger 2012 OCT 25  
Second Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
5/30231	25225-15	Zip Pen Smoke Emissio n	2014-03-11	11

Unless otherwise specified, the sampling plan is C=0.

Burst / Creep Inspection method is specified by 1100016-10.

Specification, in. H <sub>2</sub> O	Burst Date: 2014-10-17	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only				
			Time	Lane #	pouch 1	Lane #	pouch 3
19	✓	10:10	10:10	C1-8	20.3		
				C1-5	23.0		
				C1-3	13.5		
				C1-12	21.0		
				C1-11	21.8		
				C1-14	23.1		
				C1-13	19.4		
				C1-20	22.9		
				C1-19	20.5		
				C1-16	20.1		
			10:11	C1-7	13.7		

Megadyne Medical Products, Inc.	TEST PROTOCOL			Document Number
				X1150720-10
				Revision: 01
				Effective Date: 2014 MAR 27
Shipping Test – Zip Pencil			Page 19 of 20	

Appendix IV  
Seal Width Log Sheet

Catalog # 2525-10

Lot #: S130409 and S130410

409

Sample	Cavity	Front	Back	Right	Left
1	2	.357	.368	.337	.387
2	2	.369	.352	.336	.403
3	2	.362	.381	.353	.397
4	1	.381	.362	.333	.380
5	2	.398	.402	.349	.395
6	1	.369	.373	.331	.364
7	1	.364	.377	.354	.375
8	2	.364	.393	.367	.357
9	1	.377	.365	.358	.353
10	2	.372	.353	.370	.405
11	2	.365	.373	.370	.403
12	1	.371	.391	.340	.363
13	2	.388	.391	.356	.405
14	2	.379	.393	.365	.396
15	1	.374	.388	.345	.367
16		.382	.375	.356	.373
17		.374	.402	.344	.372
18		.365	.385	.353	.369
19		.379	.393	.331	.388
20		.377	.381	.346	.377
21	2	.362	.391	.344	.366
22		.380	.361	.333	.366
23	2	.369	.398	.357	.395
24	2	.377	.377	.353	.395
25	1	.366	.390	.338	.360
26	2	.380	.402	.357	.394
27	1	.380	.398	.338	.367
28	2	.362	.407	.402	.360
29		.363	.385	.346	.393
30		.373	.393	.332	.355
31		.379	.381	.357	.357
32		.368	.383	.343	.372
33	2	.376	.380	.367	.400
34	1	.363	.379	.336	.354
35	2	.356	.374	.361	.389
36	2	.389	.398	.372	.398
37	2	.377	.392	.342	.396
38	2	.377	.391	.363	.390
39	1	.382	.400	.342	.355
40	1	.362	.385	.338	.346

410

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	Shipping Test – Zip Pencil	Revision: 02
		Effective Date: <b>2014 MAR 27</b>
		Page 21 of 22

## Appendix IV Seal Width Log Sheet

Catalog # 2525-10

Lot #: 5136227

Sample	Cavity	Front	Back	Right	Left
1	1 B1-1	.12	.35	.36	.35
2	1 B1-2	.19	.36	.24	.25
3	2 B1-3	.30	.33	.25	.22
4	2 B1-4	.14	.10	.25	.25
5	1 B1-5	.30	.24	.26	.34
6	2 B1-6	.30	.20	.20	.28
7	2 B1-7	.20	.30	.26	.24
8	2 B1-8	.24	.36	.26	.24
9	1 B1-9	.32	.30	.20	.34
10	2 B1-10	.30	.25	.25	.20
11	2 B1-11	.15	.32	.30	.20
12	2 B1-12	.12	.38	.30	.22
13	1 B1-13	.20	.37	.24	.34
14	1 B1-14	.30	.33	.29	.26
15	2 B1-15	.30	.30	.24	.29
16	2 B1-16	.28	.38	.24	.24
17	1 B1-17	.20	.35	.22	.28
18	1 B1-18	.32	.27	.22	.32
19	1 B1-19	.30	.32	.25	.12
20	1 B1-20	.19	.23	.33	.33
21					
22					
23					
24					
25					
26					
27					
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		2014 MAR 27
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**Appendix IV**  
**Seal Width Log Sheet**Catalog # 2525-15Lot #: S130228

Sample	Cavity	Front	Back	Right	Left
1	1 D1-1	.28	.26	.28	.30
2	2 D1-2	.32	.22	.30	.28
3	2 D1-3	.18	.26	.30	.28
4	1 D1-4	.32	.22	.22	.30
5	2 D1-5	.28	.28	.35	.30
6	1 D1-6	.30	.32	.28	.30
7	2 D1-7	.32	.36	.30	.30
8	2 D1-11	.16	.32	.32	.36
9	1 D1-12	.32	.32	.20	.32
10	1 D1-13	0	.18	.24	.20
11	1 D1-14	.32	.22	.24	.34
12	2 D1-15	.30	.26	.28	.34
13	2 D1-16	.32	.19	.22	.36
14	1 D1-17	.34	.22	.18	.30
15	2 D1-18	.30	.24	.29	.30
16	1 D1-19	.32	.22	.24	.32
17	1 D1-20	.28	.28	.18	.28
18					
19					
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		<b>Page 21 of 22</b>

**Appendix IV**  
**Seal Width Log Sheet**Catalog # 2525-15Lot #: 313023

Sample	Cavity	Front	Back	Right	Left
1	2 C1-1	.6	.22	.20	.28
2	1 C1-2	.10	.34	.24	.26
3	2 C1-10	.30	.32	.16	.34
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
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Appendix IV V MJ 2/25/14  
Electrode/Cap Inspection Log Sheet

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

Catalog #	Pass	Fail
2525-10 Electrode	25/25/14 20	
Cap	20	

Comments: Lot # S130227

Malissa Fisher  
Inspected by:

2/7/2014  
Date completed

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#### **Appendix IV** **Electrode/Cap Inspection Log Sheet**

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

Catalog #	Pass	Fail
2525 - 15		
Electrode	17	
Cap	17	

Comments: Lot # 130228

Malissa Fisher 2/7/2014  
Inspected by: Date completed

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		<b>Revision:</b> 02
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<b>Shipping Test – Zip Pencil</b>		<b>Page 22 of 22</b>

## Appendix IV Electrode/Cap Inspection Log Sheet

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

Catalog #	Pass	Fail
2525 -15		
Electrode	3	
Cap	3	

Comments: Lot # S13623

Malissa Fisher

Inspected by:

2/7/2014

Date completed

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**APPENDIX VI**  
See attached literature

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2014 MAR 27

3500 North Main Street  
Oshkosh, WI 54903  
Phone: (920) 527-7000  
FAX: (920) 527-7002

Mark Glassett  
Megadyne Medical Products Inc.  
11506 South State Street  
Draper, Utah 84020

January 22, 2014

Dear Mark,  
This letter is in response to your request for microbial barrier information for PerfecForm™ 36615-MM. The structure of 36615-MM is below.

LLDPE / PE / PA / PE / PA / PE / LLDPE

PerfecForm™ 36615-MM is an impermeable material as defined by ISO 11607(2006) Part 1, Annex C. The ISO standard accepts all impermeable materials as microbial barriers.

Feel free to contact me with any additional questions or concerns.

Best Regards,

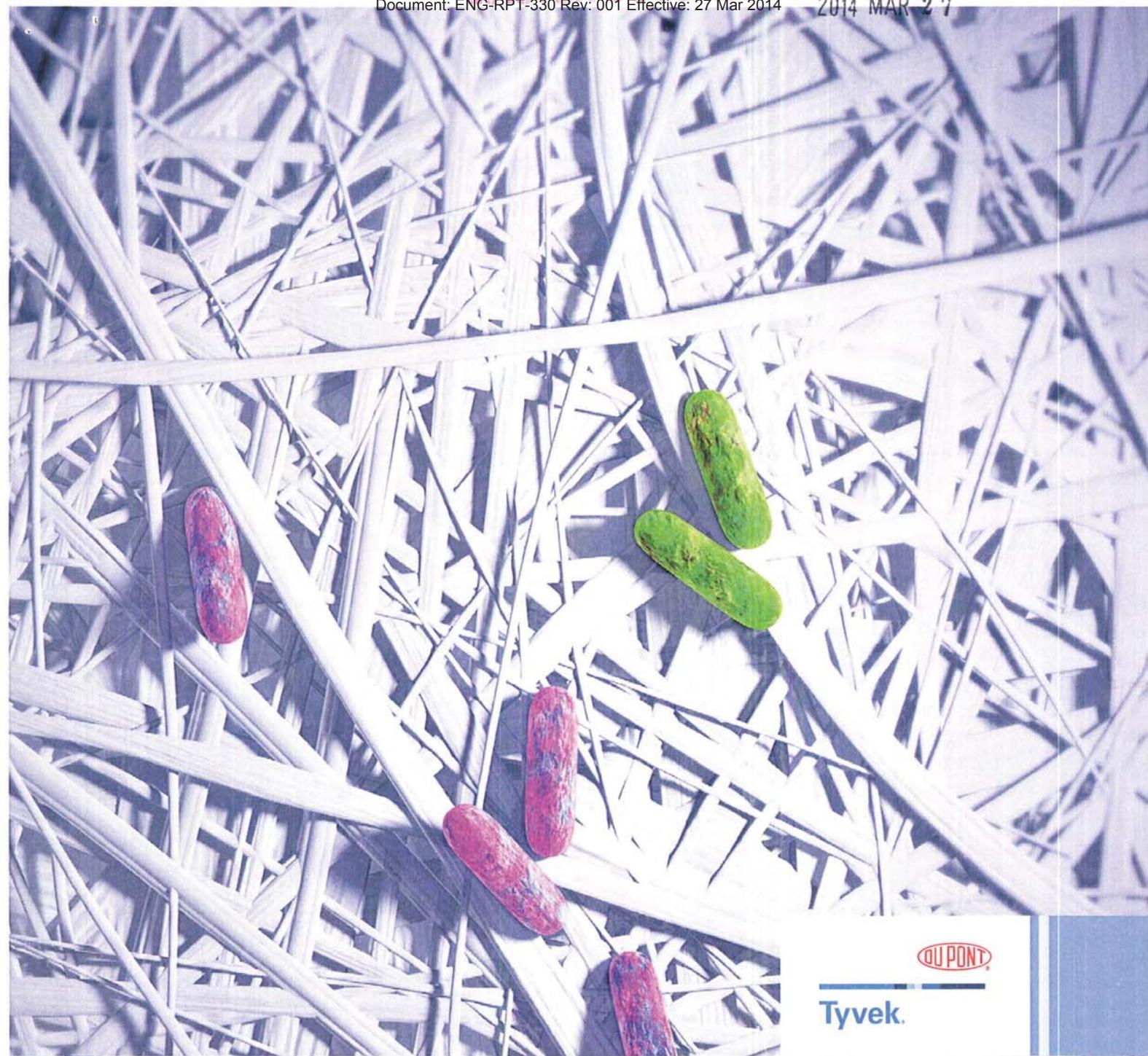
A handwritten signature in black ink that reads "Jennifer Riis".

---

Jennifer Riis  
Product Development Engineer  
Perfecseal North America  
(920) 527-7759  
jlriis@bemis.com

Perfecseal Proprietary Information

2014 MAR 27



DU PONT®

Tyvek.

## DUPONT™ TYVEK® COMPLIANCE TO ISO 11607-1:2006

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Tyvek.

## INTRODUCTION

DuPont™ Tyvek® spunbonded olefin is intended for packaging of terminally sterilized medical devices. To guide the medical device manufacturers and sterile packaging manufacturers in their selection and use of packaging, the International Standards community has promulgated the ISO 11607-1:2006 *Packaging for terminally sterilized medical devices Part 1: Materials, sterile barrier systems and packaging systems and ISO 11607-2:2006 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes*.

As the producer of Tyvek® for medical and pharmaceutical packaging, DuPont Medical and Pharmaceutical Protection has compiled documentation which demonstrates the compliance of Tyvek® with the materials portion of the ISO 11607-1:2006 standard. This will allow medical device manufacturers and sterile packaging manufacturers to focus on the package material production, final package design qualification, and the device package process validation portions of the standard. The compliance is supported by a number of DuPont Technical Information Documents (TIDs) which contain the necessary experimental data. In this preamble, the documents are described and their applicability to the various sections of the ISO 11607-1:2006 document are explained. The TIDs, which cover material testing for sterile barrier systems, can be used to demonstrate packaging compliance to this standard. Much of the information in the TIDs is presented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

The product characteristics of Tyvek® include:

- Outstanding porous microbial barrier
- Strength to weight ratio
- Moisture resistance
- Inertness to most chemicals
- Air and water vapor permeability
- Clean peeling seals
- Low linting due to continuous filaments
- Low fiber tear
- Puncture resistance

These characteristics provide high value in terminally sterilized packaging of medical devices sterilized by a wide variety of methods. Several package configurations containing Tyvek® are used within the medical device industry. Packages such as chevron peel pouches and header bags are composed of Tyvek® sealed to flat, unshaped, flexible film in a wide variety of length and width dimensions. In addition, Tyvek® is commonly used in packages made with a Form/Fill/Seal (FFS) process and equipment using rigid or flexible forming films, as well as lidding material for preformed rigid trays.

Both adhesive coated and uncoated Tyvek® are used in medical packaging. When uncoated Tyvek® is used, the film web contains the adhesive layer to form the seal between the film and the Tyvek®.

A variety of converting steps may be required prior to using Tyvek® in medical packaging. Some will have the adhesive coated onto the Tyvek® prior to use, while most will be printed, slit or die cut before incorporation into the final package.

The permeability and chemical inertness of Tyvek® allow its use in a variety of sterilization processes. The sterile barrier systems using Tyvek® are commonly sterilized using ethylene oxide (EO) gas, gamma and electron-beam radiation. In addition, steam sterilization may be used if temperatures are controlled to avoid melting the Tyvek®. Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi for 30 minutes). Emerging low-temperature sterilization methods such as: gas plasma with hydrogen peroxide, vapor phase hydrogen peroxide with peracetic acid, ozone and chlorine dioxide, require Tyvek® packaging because cellulosic porous materials are adversely affected by these strong oxidizing environments.

This document is used to demonstrate the compliance of Tyvek® with the ISO 11607-1:2006 standard. Tyvek® falls under sections 4 and 5. This document lists each clause from ISO 11607-1 that contains a requirement, followed by compliance information for the requirement. There are other DuPont documents that are referred to in this document and they are all available at [www.MedicalPackaging.DuPont.com](http://www.MedicalPackaging.DuPont.com)

## ISO 11607-1:2006 REQUIREMENTS

### 4. GENERAL REQUIREMENTS

The numbers in the following sections refer to the specific clauses in ISO 11607-1.

#### 4.2. Quality systems

**4.2.1 The activities described within this part of ISO 11607-1:2006 shall be carried out within a formal quality system.**

Tyvek® production facilities located in Richmond, VA, and Luxembourg are ISO 9001:2008 certified. As a requirement for certification, both facilities have a Quality Systems Manual. The Quality Systems Manual is an evergreen document and the controlled copy is kept on file. Our performance against it is the subject of semi-annual audits as part of retaining ISO 9001:2008 Registration, and is available to the auditors of our facilities. Changes to the manual may only be made with appropriate approvals. The current ISO 9001:2008 Registration Certificates are available at [www.MedicalPackaging.DuPont.com](http://www.MedicalPackaging.DuPont.com)

#### 4.3 Sampling

**The sampling plans used for selection and testing of packaging systems shall be appropriate to packaging systems being evaluated. Sampling plans shall be based upon statistically valid rationale.**

Sampling and physical property testing for Tyvek® 1073B, Tyvek® Asuron® (4070B), Tyvek® 1059B, Tyvek® 2FS® (4058B) and Tyvek® 4057B are conducted per procedures associated with ISO 9001:2008 quality systems registration. Samples of Tyvek® are taken at the bonder windup, identified, and delivered to the in-area lab for physical property testing.

All routine physical property tests run on bonded Tyvek® are performed in the in-area lab. Testing is intended to satisfy Product Characterization, Process Control, and Measurement Control.

Samples are managed using the laboratory information management system (LIMS). Every sample is identified with a LIMS sample label. The sample label contains all necessary information needed to track a test result back to finished product.

Tyvek® is produced in full mill rolls that are approximately 10 feet wide and have a diameter of approximately three feet. These full mill rolls are then slit into multiple smaller packages according to the customer requirements. Full mill rolls are sampled uniformly across their width (typically 12 samples/full mill roll) to calculate roll averages. Thickness measurements are based on individual values (typically 112 samples/full mill roll) versus full mill roll averages. The average thickness is determined by pooling the ~112 data points from a roll with individual data points from other rolls and averaged. Test method variance related to equipment and analysis is included in the observed values. Other sampling plans and test methods may yield different values.

#### 4.4 Test methods

**4.4.1 All test methods used to show compliance with this International Standard shall be validated and documented.**

All physical properties of Tyvek® that are used to demonstrate acceptable material for packaging terminally sterilized medical devices are measured by validated DuPont test methods that are comparable to recognized, national and international standards. DuPont conducts testing as shown in Table I.

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Table I. Test methods used for measuring material properties

Property	Comparable Standard Test Methods		Deviations from Standard Test Methods
	Richmond, VA	Luxembourg	
Basis Weight	ASTM D3776	EN ISO 536	Modified sample size.
Delamination	ASTM D2724	ASTM D2724	Modified for speed and gauge length.
Gurley-Hill Porosity	TAPPI T460 <sup>1</sup>	ISO 5636-5 <sup>2</sup>	1. Modified sample size. 2. Modified for sealing fluid characteristics.
Opacity	TAPPI T425	ISO 2471	Modified for different backing standards, area and illumination.
Thickness (individual)	ASTM D1777 <sup>1</sup>	EN ISO 534	1. 7.15 psi, 0.625-in. diameter presser foot.
Tensile and Elongation	ASTM D5035	EN ISO 1924-2	Modified for speed and gauge length.
Elmendorf Tear	ASTM D1424	EN 21974	—
Hydrostatic Head	AATCC TM 127	EN 20811	Rate of use: 60 cm H <sub>2</sub> O/min.
Mullen Burst	ASTM D774	ISO 2758	—
Bendtsen Air Permeability	ISO 5636-3	ISO 5636-3	—
Spencer Puncture	ASTM D3420	ASTM D3420	Modified for 9/16-in. (14.28-mm) probe

**4.4.2 Test method validation *shall* demonstrate the suitability of the method as used. The following elements *shall* be included:**

- Establishment of a rationale for the selection of the appropriate tests for the packaging system
- Establishment of acceptance criteria; pass/fail is a type of acceptance criterion
- Determination of test method repeatability
- Determination of test method reproducibility
- Determination of test method sensitivity for integrity tests

Equipment calibration procedures for quality critical instruments and lab measurement control are conducted per internal procedures associated with ISO 9001:2008 quality systems registration.

The establishment of test methods was based on ISO 11607-1 Appendix B recommendations for test methodology. The accuracy and reliability of test results are highly dependent on the calibration of test equipment and the control of the testing environment, sampling process, and the testing process. The DuPont standard operating procedure specifies the calibration and control system for the in-area test lab equipment to ensure data is consistently accurate. The test data on routine production samples is used to certify product meets established standards and to control processing conditions that impact physical and chemical properties. All test equipment is calibrated on a specified frequency using gauges traceable to nationally recognized standards or locally developed standards.

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The Tyvek® in-area lab controls the measurement system by using a standard sample to monitor the repeatability and stability of most instruments in the lab. This provides a reliable method for detecting significant deviations in instrument readings due to instrument failure. Following is a summary of the standard control procedure:

- A standard sample roll is selected from routine production that represents a stable process condition in spinning and bonding.
- Several samples from this roll are tested to establish control limits.
- The standard sample is tested on a regular schedule on each instrument and the results are monitored.
- Corrective action is taken when a drift is detected.

### 4.4.3 Unless specified in test methods, test samples shall be conditioned at (23 ± 1)°C and (50 ± 1) % relative humidity for 24h.

All samples used for product release are tested in a controlled laboratory environment. Because Tyvek® is hydrophobic, samples are not stabilized for 24 hours prior to testing.

## 4.5 Documentation

### 4.5.1 Demonstration of compliance with the requirements of this standard shall be documented.

### 4.5.2 All documentation shall be retained for a specified period of time. The retention period shall consider factors such as regulatory requirements, expiry date and traceability of the medical device or sterile barrier system.

All documents that illustrate the compliance of Tyvek® with ISO 11607-1:2006 are retained for a specified period of time. This time period varies depending on the type of document and is specified in our quality procedures.

## 5. MATERIALS AND PREFORMED STERILE BARRIER SYSTEMS

Tyvek® has been used to package terminally sterilized medical devices in a variety of global climates since 1972. Because it is made of high-density polyethylene fibers, it is not affected by climatic changes in humidity, temperature, or atmospheric pressure. Because its melting point is 275°F (135°C), steam sterilization must be limited to <260°F (<127°C) temperature cycles. Exposure to UV light should be limited to less than one month. Normal shipping, handling and storage conditions should be used. Compatible ink offerings and labeling systems have been developed and most major manufacturers offer them to the market.

The administration of essential ingredients is conducted per standard operating procedures, specifying responsibility leading to the implementation of a system for the set-up, receipt and release of essential materials. Each shipment of polymer is received with a Certificate of Analysis demonstrating that the specification parameters are met.

### 5.1 General requirements

#### 5.1.3 The conditions under which the material and/or preformed sterile barrier system are produced and handled shall be established, controlled and recorded, if applicable, in order to ensure that:

- a) the conditions are compatible with the use for which the material and/or sterile barrier system is designed;
- b) the performance characteristics of the material and/or sterile barrier system are maintained.

Tyvek® is a highly inert material and, once manufactured, it typically does not change unless directly exposed to UV light for more than 30 days.

**5.1.4 As the minimum, the following shall be considered:**

**a) Temperature range**

Toughness and flexibility are retained down to -100°F (-73°C). When exposed to heat, Tyvek® begins to shrink at approximately 270°F (132°C) and melts at 275°F (135°C). Under actual processing conditions, the temperature can influence the handling of the web and the range of exposures should be controlled or validated. It is suggested that the web temperature should not exceed 175°F (79°C).

**b) Pressure range**

The ability to perform over a range of pressures is a critical characteristic of Tyvek® when incorporated into a sterile barrier system (SBS). Porosity is the fabric characteristic related to pressure an SBS may experience and allows for the equilibration of pressure differentials across a sealed SBS. The extent of the porosity necessary for an SBS is an attribute only a medical device manufacturer can determine based on the sterilization processing, shipping, handling and storage the packaging system will be exposed to during its life cycle.

**c) Humidity range**

Tyvek® is hydrophobic and is not affected by moisture. Tyvek® maintains its strength regardless of humidity.

**d) Maximum rate of change of the above, where necessary**

As a packaging material, the rate of temperature, pressure and humidity changes are not applicable. These elements must be considered once Tyvek® becomes part of an SBS.

**e) Exposure to sunlight or UV light**

Physical properties of Tyvek® are degraded with extended exposure to direct sunlight (ultraviolet rays).

**f) Cleanliness**

Tyvek® is composed of essentially continuous fibers and does not generate a significant amount of lint particles under conditions of ordinary use.

**g) Bioburden**

The process of manufacturing Tyvek® allows only short periods of time when the sheet is subject to airborne particulates and microbes; therefore, the bioburden on the surface of the Tyvek® is very low. This low bioburden does not add significantly to the required sterilization time. The typical bioburden of all Tyvek® medical packaging styles is less than 100 colony forming units (cfu) per ft<sup>2</sup>.

**h) Electrostatic conductivity**

In some processing steps, Tyvek® may generate static electricity unless treated with antistatic agents. Styles intended for medical packaging do not contain an antistatic agent. Untreated styles can build a static charge during roll or sheet handling and should not be handled in areas where there is the potential for explosive vapor/air mixtures.

**5.1.5 The source, history and traceability of materials, especially recycled materials, shall be known and controlled to ensure that the finished product will consistently meet the requirements of this part of ISO 11607.**

The source history and traceability of incoming and outgoing materials are controlled by our quality control procedures. Recycled materials are not used to manufacture Tyvek® medical packaging styles.

**5.1.6 The following properties shall be evaluated:**

**a) Microbial barrier**

The microbial barrier properties of Tyvek® are superior to medical-grade papers and are well documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 3) located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

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### b) Biocompatibility and toxicological attributes

Biocompatibility and other toxicological attributes of Tyvek® medical packaging styles are acceptable and are documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

### c) Physical and chemical properties

The physical properties of Tyvek® styles intended for medical packaging can be found in specifications and miscellaneous properties tables in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 2) located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html). These specifications and miscellaneous properties serve as a guide for medical device manufacturers to determine the level of protection required for a particular device.

Because Tyvek® is made of high-density polyethylene, it is relatively chemically inert. The chemical resistance of Tyvek® to various chemicals is available at [http://www2.dupont.com/Tyvek/en\\_US/assets/downloads/tyvek\\_handbook.pdf](http://www2.dupont.com/Tyvek/en_US/assets/downloads/tyvek_handbook.pdf)

### d) Compatibility with respect to forming and sealing processes

Tyvek® has been used as a packaging material for medical devices since 1972. It is customary for the user of a sterile barrier system (SBS) to specify the strength requirements required for its use. It is intended that the package or SBS strength selected will be sufficiently strong so as to assure SBS integrity through the user's distribution, handling and storage systems. The strength of a preformed SBS seal should be determined by the manufacturer of that system. The effect of aging on seal strength is documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging*, which is available at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

### e) Compatibility with respect to the intended sterilization process(es)

Tyvek® medical packaging styles are compatible with all approved sterilization methods, including: ethylene oxide, electron-beam, gamma irradiation, steam (under controlled conditions), and low-temperature oxidative sterilization processes. The effects of sterilization on Tyvek® medical packaging styles are documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 4) located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

### f) Any shelf-life limitations for pre-sterilization and post-sterilization storage

Tyvek® medical packaging styles should be stored under the same conditions as one would store a medical device. Tyvek® should not be exposed to direct sunlight for more than 30 days.

Tyvek® is capable of maintaining package integrity and sterility for at least five years. The effects of post-sterilization storage are documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 5) located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

#### 5.1.7 Materials, e.g. wrapping materials, paper, plastic film, nonwovens, reusable fabrics, shall meet the following general performance requirements:

##### a) Materials shall be non-leaching and odorless under specified conditions of use to such an extent that neither performance nor safety is impaired and the medical devices with which they are in contact are not adversely affected.

Tyvek® is an article made of high density polyethylene (HDPE) and is odorless. Elemental analysis of selected Tyvek® styles shows various elements including heavy metals are in the range of trace amount or are non-detectable. Tyvek® medical packaging styles meet the extractable or composition requirements of various regulations such as 21CFR 177.1520, Commission Regulation (EU) N° 10/2011 and European Pharmacopoeia, Section 3.1.5.

**b) Materials shall be free of holes, cracks, tears, creases, or localized thickening and/or thinning sufficient to impair functioning.**

Standard operating procedures (SOPs) are used within the manufacturing facilities to identify and correct visual anomalies. A summary of the SOPs describing the types of anomalies seen in Tyvek® and the release standards for Tyvek® medical packaging styles are listed below. Corrective actions when an anomaly is detected are also defined.

**• Inspecting, grading, segregating and dispositioning of product**

SOPs define the roles and responsibilities required to deliver the best product possible to our customers, including; guidelines for inspecting, grading, segregating and dispositioning Tyvek®; specifications for moving sheet and stationary sheet; inspections tables describing anomalies, their causes, detection methods; and instructions related to segregating and dispositioning product when anomalies are detected.

**• Anomaly descriptions and possible causes**

SOPs are designed to give a detailed description and definition of each known anomaly, the frequency of occurrence, and detection process. There are two categories of anomalies:

**Minor:**

An anomaly that does not affect performance but should be eliminated. This anomaly will be recorded and action taken to correct and prevent the anomaly. This type of anomaly will ship to customers.

**Major:**

An anomaly that does affect performance and must not ship. This anomaly will be recorded and action taken to correct and prevent the anomaly. This type of anomaly will not ship to customers.

**• Tracing and clearing of anomalies**

Once a major anomaly is detected, the anomaly must be traced and cleared per SOPs. This prevents unacceptable material from shipping to customers.

**c) Materials shall have a basis weight (mass per unit area) which is consistent with the specified value.**

See the specification properties tables in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 2) which is available at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

**d) Materials shall exhibit acceptable levels of cleanliness, particulate matter and linting.**

Internal processes specify release limits for cleanliness and particulate matter. Tyvek® does not generate a significant amount of lint particles under conditions of ordinary use. Refer to the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 3), which is available at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

**e) Material shall comply with established specific or minimum physical properties such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.**

For Tyvek® medical packaging styles, the established specification properties are Gurley Hill, Delamination and Basis Weight. The specific values for these can be found in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 2), which is available at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html) Additional properties that are important when considering alternative materials for your specific applications can also be found in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 2).

**f) Materials shall comply with established specific chemical characteristics (such as pH value, chloride, and sulfate contents) to meet the requirements of the medical device, packaging system or sterilization process.**

Tyvek® is an article made of high density polyethylene (HDPE) and is odorless. Elemental analysis of selected Tyvek® styles shows various elements including heavy metals are in the range of trace amount or are non-detectable. Tyvek® medical packaging styles meet the extractable or composition requirements of various regulations such as 21CFR 177.1520, Commission Regulation (EU) N° 10/2011 and European Pharmacopoeia, Section 3.1.5.

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**g) Materials shall not contain or release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.**

The toxicological attributes of Tyvek® medical packaging styles are documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* (Section 4) located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

**5.1.8 In addition to the requirements given in 5.1.1 through 5.1.6, adhesive-coated materials shall meet the requirements listed below.**

Adhesive coated Tyvek® is sold by sterile packaging manufacturers and each will require a different set of process conditions to give the required package strength and integrity. The medical device manufacturer must validate the processes used for the coated product they are using.

**5.1.10 In addition to the requirements given in 5.1.1 through 5.1.7, reusable containers shall meet the requirements given below.**

Tyvek® is not designed to produce reusable containers.

### 5.2 Microbial barrier properties

**5.2.1 The impermeability of a material shall be determined in accordance with Annex C.**

Tyvek® is not considered to be an impermeable material.

**5.2.2 Demonstrating that the material is impermeable shall satisfy the microbial barrier requirements.**

Tyvek® is not considered to be an impermeable material.

**5.2.3 Porous materials shall provide an adequate microbial barrier to microorganism in order to provide integrity of the sterile barrier and product safety.**

The microbial barrier properties of Tyvek® are superior to medical-grade papers and are well documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

### 5.3 Compatibility with the sterilization process

**5.3.1 It shall be demonstrated that the materials and preformed sterile barrier system are suitable for use in the specified sterilization process(es) and cycle parameters.**

**5.3.2 The performance of the materials shall be evaluated to ensure that the material performance remains within specified limits after exposure to all the specified sterilization processes.**

Tyvek® medical packaging styles are compatible with all approved sterilization methods, including: ethylene oxide, electron-beam, gamma irradiation, steam (under controlled conditions), and low-temperature oxidative sterilization processes. The effects of sterilization on medical packaging styles are documented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* located at [http://www2.dupont.com/Medical\\_Packaging/en\\_US/tech\\_info/index.html](http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html)

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### 5.4 Compatibility with the labeling system

The labeling system *shall*:

**a) remain intact and legible until the point of use;**

Ink manufacturers have developed specific inks to print on medical packaging styles of Tyvek®. To achieve consistent, high-quality print, the appropriate ink must be used.

**b) be compatible with the materials, sterile barrier system and medical device during and after the specified sterilization process(es) and cycle parameters and *shall not* adversely affect the sterilization process;**

**c) not be printed or written in ink of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system nor change colour to an extent which renders the label illegible.**

The labeling of product made by the Tyvek® manufacturing plants is aimed at meeting the needs of our customers and contractors. It must further account for and trace product through all manufacturing steps. Labels are applied to rolls of Tyvek® during the inspection and packaging operations. These labels provide sufficient information to identify the product and to trace product processing at the manufacturing site using the package number (bar-coded) as the primary identifier.

Because the label is removed prior to final processing; the reaction of the ink and label material is not applicable.

### 5.5 Storage and transport

**5.5.1 Materials and preformed sterile barrier systems *shall* be packaged to provide the protection necessary to maintain the performance characteristics during transport and storage.**

The material wrapping system used by DuPont is designed to provide the necessary protection to the rolls through the global supply chain. This would include transport by rail, truck, ocean containers and air. The rolls are wrapped with polyethylene stretch film in either an axial or barrel method.

These methods of wrapping protect the Tyvek® rolls from contamination and damage during distribution and handling. There are no restrictions on transport and storage of Tyvek® other than avoiding direct exposure to UV light for more than 30 days.

**5.5.2 Materials and preformed sterile barrier systems *shall* be transported and stored under conditions that ensure that the performance characteristics remain within specified limits.**

This can be accomplished by:

**a) demonstrating retention of these characteristics under defined storage conditions;**

**b) ensuring that storage conditions remain within specified limits.**

There are no restrictions on transport and storage of Tyvek® other than avoiding direct exposure to UV light for more than 30 days.

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For more information about DuPont™ Tyvek® for medical and pharmaceutical packaging and to find out how we can help you with packaging and regulatory compliance, call us today at 1.800.44.TYVEK or visit us at [www.MedicalPackaging.DuPont.com](http://www.MedicalPackaging.DuPont.com)

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