



## Certificate of Analysis-TITANIUM –CRY151

**PRODUCT batch number: P725602**

Product Name:		<b>TITANIUM Working Solution</b>
Reference:		CRY/TTM/024
This is to certify that TITANIUM Working Solution bearing the Batch No: P725602 was tested on 2017.09.11 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear pale yellow liquid free of matter	Conforms
ODOUR	Chlorine like	Conforms
CLO <sub>2</sub> Concentration (ppm)	160-200	177

Product Name:		<b>TITANIUM Base Solution</b>
Reference:		MED/SOL/449
Date of Manufacture:		2017.09.11
Date of Expiry:		2019.09
This is to certify that TITANIUM Base Solution was tested on 2017.09.11 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear liquid free of matter	Conforms
SPECIFIC GRAVITY	1.000-1.200	1.021
pH	1.5 – 3.5	1.9
STERILITY	No growth	Conforms





Product Name:	<b>TITANIUM Activator Solution</b>	
Reference:	MED/SOL/450	
Date of Manufacture:	2017.09.11	
Date of Expiry:	2019.09	
This is to certify that TITANIUM Activator Solution was tested on 2017.09.11 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free of matter	Conforms
pH	10.0-11.0	10.9
SODIUM CHLORITE	0.1% +/- 0.005%	0.101
STERILITY	No growth	Conforms

Completed By:

Quality Department: *E. Andrews*

Date: *2017-10-27*

Reviewed By:

*Stelinka*

Date: *2017-10-27*



**Sterility Testing Analytical Report**

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

**Sample ID:** CRY151 Titanium Base  
**Lot No:** P725602  
**ICN:** 0917012D  
**Subcontractor's Report Number:** 2017180607

**Lab Book Reference:** ST03-105  
**Date Received:** 15Sep2017  
**Date Completed:** 16Oct2017  
**No. of samples:** 10

**Sterility Test – Membrane Filtration**

Medium	Result
Tryptone Soy Broth	No Growth
Fluid Thioglycollate Medium	No Growth

**Conclusions:**


The samples submitted comply with the test for sterility in accordance with the client's methodology.

**Results Reported by:**

  
.....  
Laboratory Technician/Designee: C.Thornton


Date: 17 OCT 2017

**Reviewed by:**

  
.....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager  
 Laboratory Manager

Date: 17 OCT 2017

**QA Approved by:**

  
.....  
 Quality Assurance  
 UK General Manager  
 Technical Manager

Date: 17 OCT 2017

**Revision History:**

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	16Oct2017

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ST03-105 ICN: 0917012D

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REVISION NO: 1

DATE: 16Oct2017

**UK**  
Deacon Park  
Moongate Road  
Knowsley  
Liverpool L33 7RX  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

**USA**  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
USA  
Tel: 001 508 540 3444  
Fax: 001 508 540 8680

**Germany**  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64546 Morfelden-Walldorf  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15

**Sterility Testing Analytical Report**

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

**Sample ID:** CRY151 Titanium Activator  
**Lot No:** P725602  
**ICN:** 0917012D  
**Subcontractor's Report Number:** 2017180606

**Lab Book Reference:** ST03-104  
**Date Received:** 18 Sep 2017  
**Date Completed:** 16 Oct 2017  
**No. of samples:** 10

**Sterility Test – Membrane Filtration**

Medium	Result
Tryptone Soy Broth	No Growth
Fluid Thioglycollate Medium	No Growth

**Conclusions:**


The samples submitted comply with the test for sterility in accordance with the client's methodology.

**Results Reported by:**

  
.....  
Laboratory Technician/Designee: C.Thornton

Date: 17 Oct 2017

**Reviewed by:**

  
.....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager  
 Laboratory Manager

Date: 17 Oct 2017

**QA Approved by:**

  
.....  
 Quality Assurance  
 UK General Manager  
 Technical Manager

Date: 17 Oct 2017

**Revision History:**

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	16 Oct 2017

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ST03-104ICN: 0917012D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 16 Oct 2017

**UK**  
Deacon Park  
Moogate Road  
Knowsley  
Liverpool L33 7RX  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

**USA**  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
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Tel: 001 508 540 3444  
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**Germany**  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64546 Morfelden-Willdorf  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 30-Aug-2017

UK33S11948217-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd  
 Unit 4C Lynx Bus Park, Fordham Rd  
 Newmarket  
 Suffolk CB8 7NY  
 UNITED KINGDOM

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1077586
Customer Reference Number:	705411
Product Description:	JET TITANIUM DV4260 25-40kGy
Validation Reference:	4260
Quantity Received:	15
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	18082017, 1 plt

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## Irradiation Data

Date and Time of Irradiation:	29-Aug-2017 22:25
Reference Dose Range kGy:	31.6 - 31.8
Calculated Minimum Dose kGy:	29.7
Calculated Maximum Dose kGy:	34.5

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Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 03-Aug-2017

UK33S11930917-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd  
Unit 4C Lynx Bus Park, Fordham Rd  
Newmarket  
Suffolk CB8 7NY  
UNITED KINGDOM

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1077585
Customer Reference Number:	705262
Product Description:	JET TRIGGER HEAD DV4258 25-40kGy
Validation Reference:	4258
Quantity Received:	32
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	Lot 25072017, 2 plts

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## Irradiation Data

Date and Time of Irradiation:	03-Aug-2017 12:23
Reference Dose Range kGy:	31.1 - 31.6
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	34.5

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Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 11-Mar-2017

UK33S11824859-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd  
 Unit 4C Lynx Bus Park, Fordham Rd  
 Newmarket  
 Suffolk CB8 7NY  
 UNITED KINGDOM

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1087393
Customer Reference Number:	704309
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	21022017, 1 plt

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## Irradiation Data

Date and Time of Irradiation:	11-Mar-2017 06:48
Reference Dose Range kGy:	33.7 - 34.3
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	36.2

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Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069