



Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY107
Reference:	CRY/DIA/040
Batch Number:	P730600
Date of Manufacture:	2017.10.30
Expiry Date:	2019.10

This is to certify that Crystel Diamond 2% solution above was tested on 2017.10.30 and found to comply with all requirements as set out in the specifications and method of analysis.

PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear Solution free of matter	Conforms
SPECIFIC GRAVITY	0.995 – 1.005	1.002
pH (neat)	8.0 – 9.0	8.4
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: Gandrews

Skolinska

Date: 2017-11-24

Date: 2017-11-24

DRF3500 CRY/DIA/041/Issue3/June 2012

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Specialists in Endotoxin and Glucan Detection

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: CRY107
Lot No: P730600
ICN: 1117001D
Subcontractor's Report Number: 2017206858

Lab Book Reference: ST03-116
Date Received: 06 Nov 2017
Date Completed: 22 Nov 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: Daniel Jennings

Date: 22 Nov 2017

Reviewed by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 23 Nov 2017

QA Approved by:



 Quality Assurance
 UK General Manager
 Technical Manager

Date: 23 Nov 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	22 Nov 2017

CONFIDENTIAL
 ST03-116

ICN: 1117001D

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 TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 22 Nov 2017

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Web: www.acciuk.co.uk

Registered in England and Wales Company Registration Number BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-Nov-2016

UK33S11753022-4-1

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1076147
Customer Reference Number:	703612
Product Description:	1000ml T/S DV4242 25-45kGy
Validation Reference:	4242
Quantity Received:	60
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	14112016, 3 plts

Irradiation Data

Date and Time of Irradiation:	26-Nov-2016 10:27
Reference Dose Range kGy:	30.0 - 31.7
Calculated Minimum Dose kGy:	28.4
Calculated Maximum Dose kGy:	34.5

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: 10-Oct-2017

UK33S11979396-1-1

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1087391
Customer Reference Number:	705707
Product Description:	Trigger spray head crystal-G DV4286 25-45kGy
Validation Reference:	4286
Quantity Received:	9
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 2017.09.30, 1 plt

Irradiation Data

Date and Time of Irradiation:	10-Oct-2017 00:05
Reference Dose Range kGy:	36.3 - 37.3
Calculated Minimum Dose kGy:	32.8
Calculated Maximum Dose kGy:	40.5

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: 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

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

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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