



Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY107
Reference:	CRY/DIA/040
Batch Number:	P709301
Date of Manufacture:	09-MAR-17
Expiry Date:	MAR-2019

This is to certify that Crystel Diamond 2% solution above was tested on 09-MAR-17 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	1.001
pH (neat)	8.0 – 9.0	8.3
STERILITY	No growth	Conforms

Completed By:

Quality Department: E Andrews

Date: 15 May 2017

Reviewed By:

[Signature]

Date: 15 MAY 17

DRF1500 CRY/DIA/041/Issue3/June 2012



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 Diamond	Lab Book Reference: ST03-75
Lot No: P709301	Date Received: 10 Apr 2017 & 13 Apr 2017
ICN: 0417005F & 0417010F	Date Completed: 12 May 2017
Subcontractor's Report Number: 2017065812	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: Sophie Hughes

Date: 12 May 2017

Reviewed by:


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

Date: 12 May 2017

QA Approved by:


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

Date: 12 May 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	12 May 2017

CONFIDENTIAL

Page 1 of 1

ST03-75
REVISION NO: 1

ICN: 0417005F & 0417010F
DATE: 12 May 2017

TSCTS044-1 Rev 2

UK
Deacon Park
Moorgate Road
Knowsley
Liverpool L33 7RN
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 Mürfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-Aug-2016

UK33S11673290-2-1

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:	1076147
Customer Reference Number:	702783
Product Description:	1000ml T/S DV4242 25-45kGy
Validation Reference:	4242
Quantity Received:	30
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 008, 1PLT

Irradiation Data

Date and Time of Irradiation:	05-Aug-2016 13:09
Reference Dose Range kGy:	32.6 - 33.5
Calculated Minimum Dose kGy:	30.9
Calculated Maximum Dose kGy:	36.4

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: 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: 03-Oct-2016

UK33S11715571-3-1

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:	703200
Product Description:	Trigger spray head crystal-G DV4286 25-45kGy
Validation Reference:	4286
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	TS HEAD CRYL-G, 1 plt

Irradiation Data

Date and Time of Irradiation:	03-Oct-2016 09:52
Reference Dose Range kGy:	34.0 - 34.2
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	37.1

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: 19-Sep-2016

UK33S11702145-2-1

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:	703090
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG001-G, 1PLT

Irradiation Data

Date and Time of Irradiation:	19-Sep-2016 11:35
Reference Dose Range kGy:	34.2 - 34.2
Calculated Minimum Dose kGy:	26.4
Calculated Maximum Dose kGy:	36.1

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