



### Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY107	
Reference:	CRY/DIA/040	
Batch Number:	P634105	
Date of Manufacture:	15-NOV-16	
Expiry Date:	NOV-2018	
This is to certify that Crystel Diamond 2% solution above was tested on 15-NOV-16 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	8.4
STERILITY	No growth	Conforms

Completed By:

Quality Department: *E Andrews*

Date: *18 Jan 2017*

Reviewed By:

*Steph*

Date: *18/1/17*

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.

<b>Sample ID:</b> CRY107 DIAMOND <b>Lot No:</b> P634105 <b>ICN:</b> 1216009D <b>Subcontractor's Report Number:</b> 2016280478	<b>Lab Book Reference:</b> ST03-52 <b>Date Received:</b> 13 DEC 2016 <b>Date Completed:</b> 03 JAN 2017 <b>No. of samples:</b> 10
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### 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: Charlotte Ray

Date: 03 Jan 2017

#### Reviewed by:

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

Date: 03 Jan 2017

#### QA Approved by:

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

Date: 04 Jan 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C RAY	03 JAN 2016

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**ST03-52**  
**REVISION NO: 1**

**ICN: 1216009D**  
**DATE: 03 JAN 2017**

**TSCTS044-1 Rev 2**

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Registered in England and Wales. Company Registration Number: BR002906



<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

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## 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

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## 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

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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



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# Certificate of Irradiation

Date Issued: 08-Sep-2015

UK33S11452158-1-1

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:	1087391
Customer Reference Number:	700218
Product Description:	Trigger spray head crystal-G DV4286 25-45kGy
Validation Reference:	4286
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1plt

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## Irradiation Data

Date and Time of Irradiation:	08-Sep-2015 04:53
Reference Dose Range kGy:	31.1 - 32.1
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	34.8

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# Certificate of Irradiation

Date Issued: 29-Aug-2016

UK33S11678232-3-1

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:	1087393
Customer Reference Number:	702828
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG 001-G, 1 plt

## Irradiation Data

Date and Time of Irradiation:	29-Aug-2016 05:43
Reference Dose Range kGy:	37.6 - 37.6
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	39.6

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  
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