



### Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY108
Reference:	CRY/DIA/040
Batch Number:	P709300
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:

Reviewed By:

Quality Department: *E Andrews*

*Steph*

Date: *9 MAY 2017*

Date: *09 MAY 2017*

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:** CRY108 Diamond  
**Lot No:** P709300  
**ICN:** 0417005F  
**Subcontractor's Report Number:** 2017065806

**Lab Book Reference:** ST03-74  
**Date Received:** 10 Apr 2017  
**Date Completed:** 02 May 2017  
**No. of samples:** 3

### 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: 02 May 2017

#### Reviewed by:

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

Date: 02 May 2017

#### QA Approved by:

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

Date: 02 May 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	02 May 2017

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Page 1 of 1

ST03-74  
 REVISION NO: 1

ICN: 0417005F  
 DATE: 02 May 2017

TSCTS044-1 Rev 2

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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 25-Mar-2016

UK33S11581642-1-1

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:	1075875
Customer Reference Number:	701775
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	28
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1075875, 1 PLT

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## Irradiation Data

Date and Time of Irradiation:	25-Mar-2016 15:01
Reference Dose Range kGy:	35.2 - 35.9
Calculated Minimum Dose kGy:	33.5
Calculated Maximum Dose kGy:	38.4

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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



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date issued: 09-Mar-2016

UK33S11548367-2-1

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:	1078033
Customer Reference Number:	701365
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	1 plt

## Irradiation Data

Date and Time of Irradiation:	09-Mar-2016 16:08
Reference Dose Range kGy:	54.9 - 54.9
Calculated Minimum Dose kGy:	37.2
Calculated Maximum Dose kGy:	59.3

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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