



Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY107	
Reference:	CRY/DIA/040	
Batch Number:	P811400	
Date of Manufacture:	2018-04-20	
Expiry Date:	2020-04-20	
This is to certify that Crystel Diamond 2% solution above was tested on 2018-04-20 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	1.000
pH (neat)	8.0 – 9.0	8.5
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E Andrews

S Zielinska

Date: 2018-05-22

Date: 2018-05-22

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
Lot No: P811400
ICN: 0418028D
Subcontractor's Report Number: 2018077479

Lab Book Reference: ST03-161
Date Received: 26 APR 2018
Date Completed: 17 MAY 2018
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:

L. Ellis
.....
Laboratory Technician/Designee: L Ellis

Date: *18 MAY 2018*

Reviewed by:

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

Date: *18 May 2018*

QA Approved by:

A. Roberts
.....
 Quality Assurance
 UK General Manager
 Technical Manager

Date: *22 May 2018*

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	17 MAY 2018

CONFIDENTIAL
ST03-161

ICN: 0418028D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 17 MAY 2018

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D-64546 Morfelden-Walldorf
Germany
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<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.steris-ast.com>

Certificate of Irradiation

Date Issued: 09-Mar-2018

UK33S12069394-3-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121921
Customer Reference Number:	706678
Product Description:	TRIGGER SPRAY HEAD CRYSTAL-G DV5170 25-45kGy
Validation Reference:	5170
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20180221, 1 plt

Irradiation Data

Date and Time of Irradiation:	09-Mar-2018 14:45
Reference Dose Range kGy:	28.7 - 34.9
Calculated Minimum Dose kGy:	26.1
Calculated Maximum Dose kGy:	38.6

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 18-Mar-2018

UK33S12076761-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121921
Customer Reference Number:	706776
Product Description:	TRIGGER SPRAY HEAD CRYSTAL-G DV5170 25-45kGy
Validation Reference:	5170
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 20180312

Irradiation Data

Date and Time of Irradiation:	18-Mar-2018 01:47
Reference Dose Range kGy:	32.4 - 32.4
Calculated Minimum Dose kGy:	29.5
Calculated Maximum Dose kGy:	35.8

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



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 07-Feb-2018

UK33S12051056-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121938
Customer Reference Number:	706435
Product Description:	BAG 001-G DV5194 25-48kGy
Validation Reference:	5194
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	48.0
Customer Unit Lot/Batch Number:	20171017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	06-Feb-2018 18:57
Reference Dose Range kGy:	38.4 - 38.4
Calculated Minimum Dose kGy:	27.5
Calculated Maximum Dose kGy:	42.8

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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