



Certificate of Analysis

Product Name:	Crystel Diamond 2% Solution CRY107	
Reference:	CRY/DIA/040	
Batch Number:	P811401	
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: Canotews

.....Skulinska.....

Date: 2018-05-22

Date: 2018-05-22

DRF1500 CRY/DIA/041/Issue3/June 2012

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ASSOCIATES OF
CAPE COD
INTERNATIONAL

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 Diamond
Lot No: P811401
ICN: 0418028D
Subcontractor's Report Number: 2018077480

Lab Book Reference: ST03-162
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:


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

Date: 18 MAY 2018

Reviewed by:


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

Date: 21 MAY 2018

QA Approved by:


.....
 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
ST03-162

ICN: 0418028D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 17 MAY 2018

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Registered in England and Wales. Company Registration Number: BR002906



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

Certificate of Irradiation

Date Issued: 19-Mar-2018

UK33S12076761-4-3

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:	1121939
Customer Reference Number:	706776
Product Description:	1000ML T/S BOTTLE DV5171 25-45kGy
Validation Reference:	5171
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 20180308

Irradiation Data

Date and Time of Irradiation:	19-Mar-2018 13:42
Reference Dose Range kGy:	33.3 - 33.6
Calculated Minimum Dose kGy:	32.0
Calculated Maximum Dose kGy:	36.6

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: 19-Mar-2018

UK33S12076761-4-1

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:	1121939
Customer Reference Number:	706776
Product Description:	1000ML T/S BOTTLE DV5171 25-45kGy
Validation Reference:	5171
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 20180308

Irradiation Data

Date and Time of Irradiation:	19-Mar-2018 13:42
Reference Dose Range kGy:	32.4 - 33.0
Calculated Minimum Dose kGy:	31.1
Calculated Maximum Dose kGy:	36.0

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

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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

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



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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

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