



Certificate of Analysis

Product Name:	Crystel Diamond CRY106
Reference:	CRY/DIA/019
Batch Number:	P811404
Date of Manufacture:	2018-04-23
Expiry Date:	2020-04-23

This is to certify that Crystel Diamond solution above was tested on 2018-04-23 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	1.030 – 1.050	1.038
pH (neat)	8.0 – 9.0	8.5
STERILITY	No growth	Conforms

Completed By:

Quality Department: Sanjiv

Date: 2018-05-29

Reviewed By:

[Signature]

Date: 2018-05-29

DRF1440 CRY/DIA/007/Issue4/June 2012





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: CRY106 Diamond
Lot No: P811404
ICN: 0418028D
Subcontractor's Report Number: 2018077481

Lab Book Reference: ST03-167
Date Received: 26 APR 2018
Date Completed: 25 MAY 2018
No. of samples: 10

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	NO GROWTH
Fluid Thioglycollate Medium	NO GROWTH

Conclusions:

Samples subcultured as precipitant seen after day 14, no growth observed at TSA 25 degrees and TSA 35 degrees plates.

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: *29 MAY 2018*

Reviewed by:

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

Date: *29 May 2018*

QA Approved by:

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

Date: *29 MAY 2018*

Revision History:

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ST03-167

ICN: 0418028D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 25 MAY 2018

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Registered in England and Wales. Company Registration Number: BR002906



DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	25 MAY 2018

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ST03-167

REVISION NO: 1

ICN: 0418028D

DATE: 25 MAY 2018

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

Certificate of Irradiation

Date Issued: 19-Mar-2018

UK33S12076761-3-2

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:	1121497
Customer Reference Number:	706776
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 20180309

Irradiation Data

Date and Time of Irradiation:	19-Mar-2018 13:43
Reference Dose Range kGy:	33.5 - 33.5
Calculated Minimum Dose kGy:	31.5
Calculated Maximum Dose kGy:	36.3

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: 25-Feb-2018

UK33S12061299-2-1

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:	1121930
Customer Reference Number:	706585
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07022018, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Feb-2018 19:32
Reference Dose Range kGy:	33.5 - 33.5
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	37.3

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



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Certificate of Irradiation

Date Issued: 22-Feb-2018

UK33S12057071-3-1

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:	1121936
Customer Reference Number:	706514
Product Description:	BAG 004-G DV5175 25-45kGy
Validation Reference:	5175
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bag 004-G, B/N: 20180131, EXP: 31.01.20, 1 pit

Irradiation Data

Date and Time of Irradiation:	22-Feb-2018 13:44
Reference Dose Range kGy:	34.7 - 34.7
Calculated Minimum Dose kGy:	26.6
Calculated Maximum Dose kGy:	37.2

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

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