



Certificate of Analysis

Product Name:	Crystel Diamond CRY106
Reference:	CRY/DIA/019
Batch Number:	P728900
Date of Manufacture:	2017-09-20
Expiry Date:	2019-09

This is to certify that Crystel Diamond solution above was tested on 2017-09-21 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	1.036
pH (neat)	8.0 – 9.0	8.5
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: *S Andrews*

[Signature]

Date: *24-11-2017*

Date: *24. Nov. 17*

DRF1440 CRY/DIA/007/Issue4/June 2012

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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	Lab Book Reference: ST03-111
Lot No: P728900	Date Received: 18 Oct 2017
ICN: 1017012F	Date Completed: 14 Nov 2017
Subcontractor's Report Number: 2017195730	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: C.Thornton

Date: 15 Nov 2017

Reviewed by:


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

Date: 17 Nov 2017

QA Approved by:


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

Date: 17 Nov 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	14 Nov 2017

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ST03-111ICN: 1017012F

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TSCTS044-1 Rev 3**

REVISION NO: 1

DATE: 14 Nov 2017

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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 09-Aug-2017

UK33S11933897-2-1

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:	1075628
Customer Reference Number:	705284
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N:26072017, 1 plt

Irradiation Data

Date and Time of Irradiation:	09-Aug-2017 05:26
Reference Dose Range kGy:	32.4 - 33.4
Calculated Minimum Dose kGy:	30.9
Calculated Maximum Dose kGy:	36.4

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: 20-Sep-2017

UK33S11963303-2-1

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:	1075625
Customer Reference Number:	705575
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	1
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN/ 20170906, 1PLT

Irradiation Data

Date and Time of Irradiation:	20-Sep-2017 16:28
Reference Dose Range kGy:	32.9 - 32.9
Calculated Minimum Dose kGy:	28.6
Calculated Maximum Dose kGy:	36.9

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 27-Sep-2017

UK33S11968580-3-1

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:	1109474
Customer Reference Number:	705597
Product Description:	BAG004 DV4850 25-45kGy
Validation Reference:	4850
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20170919, 1 PLT

Irradiation Data

Date and Time of Irradiation:	27-Sep-2017 09:13
Reference Dose Range kGy:	38.4 - 38.4
Calculated Minimum Dose kGy:	30.5
Calculated Maximum Dose kGy:	44.3

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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