



Certificate of Analysis

Product Name:	Crystel Diamond CRY106
Reference:	CRY/DIA/019
Batch Number:	P634104
Date of Manufacture:	22-NOV-16
Expiry Date:	NOV-2018

This is to certify that Crystel Diamond solution above was tested on 23-NOV-16 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:

Quality Department: *E Andrews*

Date: *18 Jan 2017*

Reviewed By:

Steph

Date: *18/1/17*



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: ST03-51
Lot No: P634104	Date Received: 13 DEC 2016
ICN: 1216009D	Date Completed: 03 JAN 2017
Subcontractor's Report Number: 2016280453	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:

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Laboratory Technician: Charlotte Ray

Date: 03 JAN 2017

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 03 Jan 2017

QA Approved by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager

Date: 04 JAN 2017

Revision History:

DCCF No.	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C RAY	03 JAN 2016

CONFIDENTIAL

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ST03-51
REVISION NO: 1

ICN: 1216009D
DATE: 03 JAN 2017

TSCTS044-1 Rev 2

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 29-Sep-2016

UK33S11715571-2-2

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:	703200
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bottle 015, 1 plt

Irradiation Data

Date and Time of Irradiation:	29-Sep-2016 01:40
Reference Dose Range kGy:	32.7 - 32.7
Calculated Minimum Dose kGy:	31.1
Calculated Maximum Dose kGy:	35.7

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: 04-Oct-2016

UK33S11715571-4-1

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:	1075625
Customer Reference Number:	703200
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CAP001-G, 1 plt

Irradiation Data

Date and Time of Irradiation:	03-Oct-2016 23:41
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	36.1

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: 04-Aug-2016

UK33S11669509-2-1

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:	1096575
Customer Reference Number:	702752
Product Description:	BAG004 DV4398 25-40kGy
Validation Reference:	4398
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG 004, 1PLT

Irradiation Data

Date and Time of Irradiation:	28-Jul-2016 00:05
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	25.2
Calculated Maximum Dose kGy:	36.2

Irradiation Release Authorised By Synergy Health plc

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