



Certificate of Analysis

| Product Name: | Crystel Diamond 2% Solution CRY107 | |
|---|---|----------|
| Reference: | CRY/DIA/040 | |
| Batch Number: | P805202 | |
| Date of Manufacture: | 2018-02-19 | |
| Expiry Date: | 2020-02-19 | |
| This is to certify that Crystel Diamond 2% solution above was tested on 2018-02-19 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 | 1.001 |
| pH (neat) | 8.0 – 9.0 | 8.4 |
| STERILITY | No growth | Conforms |

Completed By:

Reviewed By:

Quality Department: E Andrews

Stielinska

Date: 2018-03-21

Date: 2018-03-21

DRF1500 CRY/DIA/041/Issue3/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: CRY107 Diamond
Lot No: P805202
ICN: 0218022D
Subcontractor's Report Number: 2018036480

Lab Book Reference: ST03-139
Date Received: 23 Feb 2018
Date Completed: 20 Mar 2018
No. of samples: 10

Sterility Test – Membrane Filtration

| Medium | Result |
|-----------------------------|-----------|
| Tryptone Soy Broth | No growth |
| Fluid Thioglycoliate 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: Sophie Hughes


Date: 20 Mar 2018

Reviewed by:


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

Date: 20 Mar 2018

QA Approved by:


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

Date: 20 Mar 2018

Revision History:

| DCCF No: | Revision: | Description: | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A | 1 | Revision 1, no changes | S. Hughes | 20 Mar 2018 |

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ST03-139

ICN: 0218022D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 20 Mar 2018

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Registered in England and Wales. Company Registration Number: BR002906



<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: 11-Jan-2018

UK33S12037910-2-1

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: | 706246 |
| Product Description: | TRIGGER SPRAY HEAD CRYSTAL-G DV5170 25-45kGy |
| Validation Reference: | 5170 |
| Quantity Received: | 8 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | B/N: 21122017, EXP: 20191230, 1 plt |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 11-Jan-2018 07:30 |
| Reference Dose Range kGy: | 31.3 - 31.4 |
| Calculated Minimum Dose kGy: | 28.5 |
| Calculated Maximum Dose kGy: | 34.7 |

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: 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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