





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

Certificate of Irradiation

Date Issued: 09-Apr-2018

UK33S12087515-1-1

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

Flexible Medical Packaging Ltd
Unit 8, White Cross Ind Estate
Hightown
Lancaster
Lancashire LA1 4XS
UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106483
Customer Reference Number:	P030744
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	545
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18087, 44851, INC 5 SAMPLES, 10 PLTS

Irradiation Data

Date and Time of Irradiation:	08-Apr-2018 22:35
Reference Dose Range kGy:	36.9 - 37.3
Calculated Minimum Dose kGy:	29.2
Calculated Maximum Dose kGy:	42.2

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: 16-Apr-2018

UK33S12091148-1-1

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

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UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106483
Customer Reference Number:	P030825
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	161
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18087 44851, 3 PLTS

Irradiation Data

Date and Time of Irradiation:	16-Apr-2018 00:58
Reference Dose Range kGy:	35.6 - 36.0
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	40.7

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

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Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 17 Apr 2018
Date Tested: 18 Apr 2018
Date Test Completed: 18 Apr 2018
Purchase Order: 30842

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0042100/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 17/04/2018
Test Article: Clearklens DE
Sample Code: FMP18087 44851
Batch Ref: 9271
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	77 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.3 2.6.14, USP 40 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM01-01

Approval is provided by Electronic Signature. Their name and position is shown below.

 BSc, CBiol, MRSB

Date: 19 Apr 2018 11:03:08

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 17 Apr 2018
Date Tested: 30 Apr 2018
Date Test Completed: 14 May 2018
Purchase Order: PO30842

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0042100/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 17/04/2018
Test Article: Clearklens DE
Sample Code: FMP18087 44851
Batch Ref: 9271
Qty Received: 20 x 900mL Bottles (+1 Spare)

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM03

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name and position is shown below.

CBiol, MRSB

Date: 15 May 2018 14:45:35

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology