



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 27-Mar-2014

UK32S11129505-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 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:	1002735
Customer Reference Number:	PO21912
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.1624
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	8 X FMP B/NO: WO36011 - THURS 13.03.14 2PLTS LOT 5

Irradiation Data

Date and Time of Irradiation:	27-Mar-2014 12:22
Reference Dose Range kGy:	34.9 - 35.4
Calculated Minimum Dose kGy:	28.9
Calculated Maximum Dose kGy:	37.0

Items irradiated under WO36011 will be used in finished product batch code FMP14098 36010

E. Gwynne

Irradiation Release Authorised By Synergy Health plc

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



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: 15 Apr 2014
Date Tested: 27 Apr 2014
Date Test Completed: 11 May 2014
Purchase Order: PO22113

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0016130/1
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 15/04/2014
Test Article: Bi-Spore Base
Sample Code: -
Batch Ref: FMP14098 36010
Qty Received: 20 x 100mL Bottles

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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 100 mL
Product Standard Data Sheet	FG047/psd	FM05

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

C Moore

Date: 12 May 2014 17:27:01

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0016130

Certificate of Analysis - OSMM

Print Number: P0019777

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ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Winchester Road, Wickham, Fareham, Hampshire



Wickham Laboratories

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
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Lancaster
LA1 4XS

Date Received: 15 Apr 2014
Date Tested: 27 Apr 2014
Date Test Completed: 11 May 2014
Purchase Order: PO22113

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0016130/2
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 15/04/2014
Test Article: Bi-Spore Activator
Sample Code: -
Batch Ref: FMP14098 36010
Qty Received: 20 x 100mL Bottles

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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 100 mL
Product Standard Data Sheet	FG047/psd	FM04

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

Date: 12 May 2014 17:27:01

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0016130

Certificate of Analysis - OSMM

Print Number: P0019777

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ISO
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Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Winchester Road, Wickham, Fareham, Hampshire



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 7/4/14

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP14078 36010
Production Date	04/2014
Expiration Date	04/2015

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
pH (100% 20°C)	JDM001	9.0	12.5	11.8
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	162 ppm

On behalf of Diversey site Quality Manager	Name :	C. P. S. de Vries
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator	Version : 01	Date of issuing : October 1 st 2012
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Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 9/4/14

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP14098 36010
Production Date	04/2014
Expiration Date	04/2015

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
pH (100% 20°C)	JDM001	1.5	2.5	1.9
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	C. Pascoe, Opa Linckmeier
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Base	Version : 01	Date of issuing : September 27 th 2012
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