synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 28-Apr-2014 **UK32S11147103-1-1**

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:	P022128
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:	LOT 1; 2 PLTS; THUR 17.04.14; WO36086

Irradiation Data

Date and Time of Irradiation:	28-Apr-2014 09:37
Reference Dose Range kGy:	33.2 - 33.9
Calculated Minimum Dose kGy:	27.5
Calculated Maximum Dose kGy:	35.4

Items irradiated under WO36086 will be used in finished product batch code FMP14126 36087 E Gaughan - 11.06.14

Irradiation Release Authorised By Synergy Health plc

Wickham Laboratories
Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

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

Date Received: 12 Jun 2014
Date Tested: 20 Jun 2014
Date Test Completed: 04 Jul 2014
Purchase Order: PO22368

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017080/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 12/06/2014
Test Article: Bi Spore Activator
Sample Code: FMP14126 36087
Batch Ref: 470268
Qty Received: 20 x 100mL

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 50 mL
Product Standard Data Sheet	FG047/psd	FM04

Comments
Test carried out according to current Pharmacopoeias.

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

CMoore Date: 04 Jul 2014 15:31:32

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

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

Date Received: 12 Jun 2014
Date Tested: 20 Jun 2014
Date Test Completed: 04 Jul 2014
Purchase Order: PO22368

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017080/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 12/06/2014
Test Article: Bi Spore Base
Sample Code: FMP14126 36087
Batch Ref: 466788
Qty Received: 20 x 100mL

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 50 mL
Product Standard Data Sheet	FG047/psd	FM05

Comments
Test carried out according to current Pharmacopoeias.

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

CMoore Date: 04 Jul 2014 15:31:32

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Activator first off
Base first off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 7/5/14

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP14126 36087
Production Date	05/2014
Expiration Date	05/2015

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 Lower - Upper		Results
Appearance	Visual	Clear Colourless Liquid		clear colourless liquid
pH (100% 20°C)	JDM001	1.5	2.5	1.8
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	[illegible], Olga Kuchmen-
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

Activator First off
Base First off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 2/5/14

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	EMP14126 36087
Production Date	05/2014
Expiration Date	05/2015

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 Lower	Limits Upper	Results
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
pH (100% 20°C)	JDM001	9.0	12.5	11.9
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 :	Olga Klischnew
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature