



Diversey Europe Operations BV

 Maarssebroeksedijk 2  
 3542 DN Utrecht  
 The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 4.04.2014

<b>Product Name</b>	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
<b>Product Code</b>	7515828
<b>Batch Number</b>	FMP 14087 / 36009
<b>Production Date</b>	03/2014
<b>Expiration Date</b>	03/2015

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	175.5

On behalf of Diversey site Quality Manager	Name :	Alpa Kirchner, C. Alpa
	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 <sup>st</sup> 2012
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Base First off



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## CERTIFICATE OF ANALYSIS

Date: 4.04.2014

<b>Product Name</b>	CLEARKLENS BI-SPORE BASE SOLUTION VH26
<b>Product Code</b>	7515828
<b>Batch Number</b>	FMP 14087/36009
<b>Production Date</b>	03/2014
<b>Expiration Date</b>	03/2015

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	1.7
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	Olga Linchen, C. HSCOR
	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 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 25-Mar-2014

UK32S11127701-1-1

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:	P021912
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 6; 2 PLTS; THUR 13.03.14; B/NO. WO36008

## Irradiation Data

Date and Time of Irradiation:	25-Mar-2014 22:26
Reference Dose Range kGy:	34.4 - 35.2
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	36.8

Items irradiated under WO36008 will be used in finished product batch code

FMP14087 36009

*E. Gargan - 09-04-2014*

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

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
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Alt. Telephone: +44(0)1329 832511  
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mail@wickhamlabs.co.uk  
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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 08 Apr 2014  
**Date Tested:** 15 Apr 2014  
**Date Test Completed:** 29 Apr 2014  
**Purchase Order:** 22033

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0015984/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 08/04/2014  
**Test Article:** Bi-Spore Activator  
**Sample Code:** 466787  
**Batch Ref:** FMP14087 36009  
**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 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.

Date: 30 Apr 2014 16:38:50

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015984

Certificate of Analysis - OSMM

Print Number: P0019570

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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



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Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 08 Apr 2014  
**Date Tested:** 15 Apr 2014  
**Date Test Completed:** 29 Apr 2014  
**Purchase Order:** 22033

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0015984/2  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 08/04/2014  
**Test Article:** Bi-Spore Base  
**Sample Code:** 466788  
**Batch Ref:** FMP14087 36009  
**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 50 mL
Product Standard Data Sheet	FG047/psd	FM05

### Comments

Test carried out according to current Pharmacopoeias.

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Date: 30 Apr 2014 16:38:50

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015984

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Registered Office: Winchester Road, Wickham, Fareham, Hampshire