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: 6/4/16

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP16097 40067
Production Date	06/04/2016
Expiration Date	EXP 06/04/2018

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	12.4
Specific Gravity (20°C)	JDM004	1.004	1.020	1.011
Potential Chlorine Dioxide (ppm)		100	180	176 APM

On behalf of Diversey site Quality Manager	Name :	Alisroe Patrycja
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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Base first off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 8427

CERTIFICATE OF ANALYSIS

Date: 7/4/16

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP16097 40067
Production Date	06/04/2016
Expiration Date	EXP 06/04/2018

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	1.6
Specific Gravity (20°C)	JDM004	1.010 1.030	1.019

On behalf of Diversey site Quality Manager	Name :	C Pascoe Pawlyszyn
	Position	Quality Control Inspector

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synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 07-Mar-2016 **UK32S11577051-1-1**

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

EN ISO 11137-1:2015 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:	PO26124
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:	FMP BATCH NO: WO40069 THURS 3RD MAR 2016 2 PLTS LOT 4

Irradiation Data

Date and Time of Irradiation:	06-Mar-2016 20:15
Reference Dose Range kGy:	33.1 - 33.2
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	34.7

Items irradiated under WO40069 will be used in finished batch code: FMP16097 40067

L Gallagher. 12.04.16

Irradiation Release Authorised By Synergy Health plc

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

Date Received: 13 Apr 2016
Date Tested: 20 Apr 2016
Date Test Completed: 04 May 2016
Purchase Order: 26354

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0028383/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 13/04/2016
Test Article: Bi-Spore Activator
Sample Code: FMP16097 40067
Batch Ref: 521320
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 8.0 2.6.1, USP 38 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

Date: 05 May 2016 12:20:44

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

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Ms D Henderson
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Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 13 Apr 2016
Date Tested: 20 Apr 2016
Date Test Completed: 04 May 2016
Purchase Order: 26354

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0028383/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 13/04/2016
Test Article: Bi-Spore Base
Sample Code: FMP16097 40067
Batch Ref: 521321
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 8.0 2.6.1, USP 38 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

Date: 05 May 2016 12:20:44

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology