FIRST OFF

Diversey Europe Operations BV
Maarssenbroeksedijk 2
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The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 01.02.2018

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7514852
Batch Number	FMP18024 44374
Production Date	24/01/2018
Expiration Date	EXP 24/01/2020

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 (neat solution)	DM001	1.5	2.5	2.2
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	Karolanda Partyka
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

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CERTIFICATE OF ANALYSIS

Date: 01.02.2018

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7514852
Batch Number	FMP 18024 44374
Production Date	24/01/2018
Expiration Date	EXP 24/01/2020

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 (neat solution)	DM001	9.0	12.5	12.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	145.125

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

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
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Telephone: +44(0)1329 226600
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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: 07 Feb 2018
Date Tested: 14 Feb 2018
Date Test Completed: 28 Feb 2018
Purchase Order: 30443

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040728/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/02/2018
Test Article: Bi-Spore Activator
Sample Code: FMP18024 44374
Batch Ref: 595594
Qty Received: 20 x 100mL Bottles + 2 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 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 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

BSc CBiol MRSB

Date: 05 Mar 2018 12:04:47

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

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

Date Received: 07 Feb 2018
Date Tested: 14 Feb 2018
Date Test Completed: 28 Feb 2018
Purchase Order: 30443

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040728/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/02/2018
Test Article: Bi-Spore Base
Sample Code: FMP18024 44374
Batch Ref: 587518
Qty Received: 20 x 100mL Bottles + 2 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 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 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

BSc, CBiol, MRSB

Date: 05 Mar 2018 12:04:47

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 17-Jan-2018 **UK33S12030190-1-2**

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:	1106825
Customer Reference Number:	P030170
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO44376, 1 plt
Other Process Details:	This product has received an underdose Reference S12041161-1-1 delivered a top up dose of 3.8-4.6kGy Total certifiable minimum dose: 28.7kGy Total certifiable maximum dose: 36.0kGy

Irradiation Data

Date and Time of Irradiation:	22-Dec-2017 18:04
Reference Dose Range kGy:	30.1 - 30.8
Calculated Minimum Dose kGy:	24.9
Calculated Maximum Dose kGy:	31.4

Items irradiated under WO44376, Will be used in finished product batch FMP18025 44374 C Pascoe

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