First off

Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 04/03/2019

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7514852
Batch Number	FMP19063, 47002
Production Date	04.03.2019
Expiration Date	EXP 04/03/2021

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	2.4
Specific Gravity (20°C)	DM004	1.010	1.030	1.014

On behalf of Diversey site Quality Manager	Name :	J. Slavon Pantyüs
	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: 04/03/2019

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7514852
Batch Number	FMP19063, 47002
Production Date	04.03.2019
Expiration Date	EXP 04/03/2021

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 (neat solution)	DM001	9.0	12.5	11.6
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	135

On behalf of Diversey site Quality Manager	Name :	J. Staron, [signature]
	Position	Quality Control Inspector

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

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CERTIFICATE OF ANALYSIS

Date: 04/03/2019

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7514852
Batch Number	FMP19063. 47002
Production Date	04.03.2019
Expiration Date	EXP 04/03/2021

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	11.4
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	158.6

On behalf of Diversey site Quality Manager	Name :	J. Slavon Partycka
	Position	Quality Control Inspector

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CERTIFICATE OF ANALYSIS

Date: 04.03.2019

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7514852
Batch Number	FMP 19063 , 47002
Production Date	04.03.2019
Expiration Date	EXP 04/03/2021

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.021

On behalf of Diversey site Quality Manager	Name :	J. Stawon Partyska
	Position	Quality Control Inspector

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

Date Received: 12 Mar 2019
Date Tested: 01 Apr 2019
Date Test Completed: 15 Apr 2019
Purchase Order: 32737

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0047671/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 12/03/2019
Test Article: Bi-Spore
Sample Code: FMP19063 47002 (Base)
Batch Ref: 622518
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 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05-02

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

BSc. CBiol MRSB

Date: 23 Apr 2019 10:02:31

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

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: 12 Mar 2019
Date Tested: 01 Apr 2019
Date Test Completed: 15 Apr 2019
Purchase Order: 32737

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0047671/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 12/03/2019
Test Article: Bi-Spore
Sample Code: FMP19063 47002 (Activator)
Batch Ref: 610101
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 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04-02

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

BSc. CBiol MRSB

Date: 23 Apr 2019 10:02:31

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1525A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 COMPONENTS DV4725	WO47008	8	Case

Validation Reference Number: 4725

PO Number: 07/02/2019

Processing Run Start Date: 13-Feb-19 03:08 PM

Processing Run End Date: 13-Feb-19 09:18 PM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**26.6**
Reference Dose Range (kGy):	**30.2- 39.2**	**Calculated Max Dose (kGy):**	**33.4**

Other Information

WO47008, 1 PLT. PO32552.

Signature Manifest

Reviewed and E-Signed By: **Sara Burchill (Quality Administrator)**

Date/Time E-Signed: 2019-02-14 03:01 PM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

Items irradiated under WO47008 will be used in finished product batch FMP19063 47002.