FIRST OFF

Diversey Europe Operations BV
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CERTIFICATE OF ANALYSIS

Date: 03.04.2019

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7515828
Batch Number	FHP19093, 47003
Production Date	03/04/2019
Expiration Date	EXP 03/04/2021

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	11.7
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	141.45

On behalf of Diversey site Quality Manager	Name :	Nawobuda, J Stawa
	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: 03.04.2019

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7515828
Batch Number	FHP 19093, 47003
Production Date	03/04/2019
Expiration Date	EXP 03/04/2021

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	1.7
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	J. Stavan, Navabuvda
	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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Ms D Henderson
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Unit 8
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 10 Apr 2019
Date Tested: 30 May 2019
Date Test Completed: 13 Jun 2019
Purchase Order: 32902

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048192/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/04/2019
Test Article: Bi-Spore Activator
Sample Code: FMP19093 47003
Batch Ref: 636836
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 42 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05-02

Comments

Corrected Certificate of Analysis to LR0048192/2 authorised on 18/06/2019 due to the client supplying incorrect batch number.

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

BSc. CBiol. MRSB

Date: 21 Jun 2019 11:51:21

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

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Unit 8
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LA1 4XS

Date Received: 10 Apr 2019
Date Tested: 30 May 2019
Date Test Completed: 13 Jun 2019
Purchase Order: 32902

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048192/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/04/2019
Test Article: Bi-Spore Base
Sample Code: FMP19093 47003
Batch Ref: 636835
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 42 <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: 18 Jun 2019 15:58:05

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1844A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 COMPONENTS DV4725	WO47007	8	Case

Validation Reference Number: 4725

PO Number: PO32671

Processing Run Start Date: 09-Mar-19 03:58 AM

Processing Run End Date: 09-Mar-19 10:22 AM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**27.2**
Reference Dose Range (kGy):	**30.2- 39.2**	**Calculated Max Dose (kGy):**	**34.5**

Other Information

WO47007, 1 PLT

Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-03-11 11:21 AM

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 WO47007 will be used in finished batch code Fmp19093 47003

Olga Kirchner