



Diversey Europe Operations BV
Maarssebroeksedijk 2
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The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 30.04.2019

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP19120, 47106
Production Date	30/04/2019
Expiration Date	EXP 30/04/2021

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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
pH (neat solution)	DM001	9.0	12.5	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	141.75

On behalf of Diversey site Quality Manager	Name :	Narabunda Parthasarathy
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
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CERTIFICATE OF ANALYSIS

Date: 30.04.2019

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FHPI9120.47106
Production Date	30/04/2019
Expiration Date	EXP 30/04/2021

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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	1.5	2.5	2.3
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	Patty Esler, J. Stawon
	Position	Quality Control Inspector

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

Contract Analytical Services

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Hampshire PO13 0AU England
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mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

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

Date Received: 09 May 2019
Date Tested: 03 Jun 2019
Date Test Completed: 17 Jun 2019
Purchase Order: PO33080

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048610/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 09/05/2019
Test Article: BI-Spore Activator
Sample Code: FMP19120 47106
Batch Ref: 636836
Qty Received: 20 x 100 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, C Biol, MRSB

Date: 18 Jun 2019 15:57:20

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

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

Date Received: 09 May 2019
Date Tested: 03 Jun 2019
Date Test Completed: 17 Jun 2019
Purchase Order: PO33080

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048610/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 09/05/2019
Test Article: Bi-Spore Base
Sample Code: FMP19120 47106
Batch Ref: 636835
Qty Received: 20 x 100 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 15:57:20

 Mrs P. Pham-Lengoc
 Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1620A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO47107	8	Case

Validation Reference Number: 4725

PO Number: PO32591

Processing Run Start Date: 21-Feb-19 03:51 AM

Processing Run End Date: 21-Feb-19 10:26 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.3
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.0

Other Information

WO47107, 1 PLT

Signature Manifest

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

Date/Time E-Signed: 2019-02-22 08:54 AM

Document Content Revision: 2

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 WO47107 will be used in finished batch code Fmp19120 47106

Olga Kirchner