



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 24.01.2019

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP19024_46275
Production Date	24/01/2019
Expiration Date	EXP 24/01/2021

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	1.6
Specific Gravity (20°C)	DM004	1.010	1.030	1.014

On behalf of Diversey site Quality Manager	Name :	Kavaburda Poulty
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
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## CERTIFICATE OF ANALYSIS

Date: 24/01/2019

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FHP19024.46275
Production Date	24/01/2019
Expiration Date	EXP 24/01/2021

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	1.006
Potential Chlorine Dioxide (ppm)		100	180	148.5

On behalf of Diversey site Quality Manager	Name :	U. Narabinda Pantyusko
	Position	Quality Control Inspector

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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	1.014

On behalf of Diversey site Quality Manager	Name :	Marabinda Partiyusta
	Position	Quality Control Inspector

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Product Code	7514852
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Production Date	24/01/2019
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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	10.0
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	141.75

On behalf of Diversey site Quality Manager	Name :	Elkavabunda, Partiyusta
	Position	Quality Control Inspector

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# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

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:** 29 Jan 2019  
**Date Tested:** 14 Feb 2019  
**Date Test Completed:** 28 Feb 2019  
**Purchase Order:** 32496

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0046950/7  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 29/01/2019  
**Test Article:** BI Spore Activator  
**Sample Code:** FMP19024 46275  
**Batch Ref:** 622519  
**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	FM04-01

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

CBlal MRSB

Date: 04 Mar 2019 15:00:35

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

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:** 29 Jan 2019  
**Date Tested:** 06 Feb 2019  
**Date Test Completed:** 20 Feb 2019  
**Purchase Order:** 32496

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0046950/6  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 29/01/2019  
**Test Article:** Bi Spore Base  
**Sample Code:** FMP19024 46275  
**Batch Ref:** 610100  
**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	FM05-01

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

 Mrs C Moore

Date: 26 Feb 2019 16:22:00

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1051A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO46274	8	Case

Validation Reference Number: 4725

PO Number: PO32313

Processing Run Start Date: 03-Jan-19 08:27 PM

Processing Run End Date: 04-Jan-19 02:26 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.0
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.5

## Signature Manifest

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

Date/Time E-Signed: 2019-01-14 09:29 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 loaded WO46274/WO46275