

First off



Diversey Europe Operations BV  
 Maarssebroeksedijk 2  
 3542 DN Utrecht  
 The Netherlands

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

### CERTIFICATE OF ANALYSIS

Date: 2.11.18

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 18306 46138
Production Date	02/11/2018
Expiration Date	Exp. 02/11/2020

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		Results
		Lower	Upper	
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	1.008
Potential Chlorine Dioxide (ppm)		100	180	148.5 ppm

On behalf of Diversey site Quality Manager	Name :	Olga Lineman, Balyus
	Position	Quality Control Inspector

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

Date: 6.11.18

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FKP 18306 46188
Production Date	02/11/2018
Expiration Date	Exp 02/11/2020

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		Results
		Lower	Upper	
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	1.016

On behalf of Diversey site Quality Manager	Name :	<i>exp. Koenen, P. J. J. S.</i>
	Position	Quality Control Inspector

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

**Date Received:** 13 Nov 2018  
**Date Tested:** 20 Nov 2018  
**Date Test Completed:** 04 Dec 2018  
**Purchase Order:** 32091

**CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0045763/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 13/11/2018  
**Test Article:** Bi-Spore Activator  
**Sample Code:** FMP18306 46138  
**Batch Ref:** 616965  
**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 6.2.1, 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.

*C Moore* CBiol MRSB

Date: 08 Dec 2018 15:03:15

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



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

**Date Received:** 13 Nov 2018  
**Date Tested:** 20 Nov 2018  
**Date Test Completed:** 04 Dec 2018  
**Purchase Order:** 32091

**CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0045763/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 13/11/2018  
**Test Article:** Bi-Spore Base  
**Sample Code:** FMP18306 46138  
**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 6.2.1, 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.

*JM Moore* CBiol. MRSB

Date: 08 Dec 2018 15:03:15

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 27-Oct-2018

UK33S12184414-2-2

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:	P031918
Product Description:	BISP 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:	WO46139, 1 PLT

### Irradiation Data

Date and Time of Irradiation:	27-Oct-2018 00:20
Reference Dose Range kGy:	33.4 - 33.7
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	34.4

Items irradiated under WO46319, will be used in finished product batch FMP18306 46138

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

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069