



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 03-08-2019

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP19212, 47482
Production Date	31.07.2019
Expiration Date	EXP 31/07/2021

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	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	145.125 ppm

On behalf of Diversey site Quality Manager	Name :	Y. Stanon Karabude
	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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First off



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## CERTIFICATE OF ANALYSIS

Date: 03.08.2019

Product Name	CLEARLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP19212 47482
Production Date	31.07.2019
Expiration Date	EXP 31/07/2021

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	2.2
Specific Gravity (20°C)	DM004	1.010	1.030	1.014

On behalf of Diversey site Quality Manager	Name :	J. Staven Novakovic
	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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## STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4016A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO47483	16	Case
Validation Reference Number: 4725			

Processing Run Start Date: 09-Jul-19 08:40 PM

Processing Run End Date: 10-Jul-19 02:54 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.5
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.4

**Gamma Process Run Approval authorized by STERIS**

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 WO47483 will be used in finished batch Fmp19212 47482

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Alison Siddle

**Report of Tests on:** BI-SPORE (Activator)

**Sample Description:** Sample Code: FMP19212 47482

**Lucideon Sample Number:** (194680)-36505

**Lucideon Report Number:** (194680)-36505/MFEP

**Issue Number:** 1

**Date Logged:** 21-Aug-2019

**Order Number:** PO33752

**Date Reported:** 03-Dec-2019

**Date(s) of Test(s):** 17-Nov-2019 to 03-Dec-2019

### Sterility Testing

Membrane Filtration EP

## Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report**

Natalie Boot 03-Dec-19

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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Lucideon Limited  
Queens Road, Penkhull  
Stoke-on-Trent  
Staffordshire ST4 7LQ

T +44 (0)1782 764428  
enquiries@lucideon.com  
www.lucideon.com

# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Alison Siddle

**Report of Tests on:** BI-SPORE (Base)

**Sample Description:** Sample Code: FMP19212 47482

**Lucideon Sample Number:** (194680)-36054

**Lucideon Report Number:** (194680)-36054/MFEP

**Issue Number:** 1

**Date Logged:** 21-Aug-2019

**Order Number:** PO33752

**Date Reported:** 03-Dec-2019

**Date(s) of Test(s):** 17-Nov-2019 to 03-Dec-2019

### Sterility Testing

Membrane Filtration EP

### Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report**

Natalie Boot 03-Dec-19

Mrs Natalie Boot

**Senior Business Support Assistant**

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