



Diversey Europe Operations BV  
Maarssenbroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 24 March 2025

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP25083	61853	
Production Date	24/03/2025		
Expiration Date	EXP 24/03/2027		

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	12.0
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide		100	180	135

On behalf of Diversey site Quality Manger	Name:	Justyna Staron      Natalia Traichel
	Position	Quality Control Inspector

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

COA Template	Version : 04	Date of issuing : March 11th 2019
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## CERTIFICATE OF ANALYSIS

Date: 25 March 2025

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP25083	61853	
Production Date	24/03/2025		
Expiration Date	EXP 24/03/2027		

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	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manger	Name:	Justyna Staron      Natalia Traichel
	Position	Quality Control Inspector

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COA Template	Version : 04	Date of issuing : March 11th 2019
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STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)  
Gamma Process Run ID 2173-54614A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	61855 - STR001537	15	Case
Validation Reference Number: 5857			

Processing Run Start Date 07-Mar-2025 7:42 PM  
Processing Run End Date 08-Mar-2025 1:48 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	31.7
Reference Dose Range (kGy)	26.1 - 35.8	Calculated Max Dose (kGy)	37.9

PO Number: 410188

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

**Gamma Process Run Approval authorized by STERIS**  
DateTime Esigned 08-Mar-2025 6:34 AM

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 WO61855 will be used in finished batch Fmp25083 61853.

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs. Olga Kirchner

**Report of Tests on:** Bi-Spore Activator

**Sample Description:** Sample Code: Fmp25083 61853

**Lucideon Sample Number:** N251461 - 1

**Lucideon Report Number:** N251461 - 1/MFEP

**Issue Number:** 1

**Date Logged:** 03-Apr-2025

**Order Number:** 410393

**Date Reported:** 28-Apr-2025

**Date(s) of Test(s):** 09-Apr-2025 to 23-Apr-2025

**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**

Signed by:  
*Natalie Boot*  
 Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 28 April 2025 | 12:41 BST  
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

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Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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Reg. England 1960455

# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs. Olga Kirchner

**Report of Tests on:** Bi-Spore Base

**Sample Description:** Sample Code: Fmp25083 61853

**Lucideon Sample Number:** N251461 - 2

**Lucideon Report Number:** N251461 - 2/MFEP

**Issue Number:** 1

**Date Logged:** 03-Apr-2025

**Order Number:** 410393

**Date Reported:** 28-Apr-2025

**Date(s) of Test(s):** 09-Apr-2025 to 23-Apr-2025

**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

Signed by:

*Natalie Boot*

Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 28 April 2025 | 12:41 BST  
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

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### Certificate Of Completion

Envelope Id: 7295FBD4-73AA-4233-99DA-E4F36430DC86

Status: Completed

Subject: N251461

Source Envelope:

Document Pages: 3

Signatures: 3

Envelope Originator:

Certificate Pages: 1

Initials: 0

Natalie Boot

AutoNav: Enabled

Queens Road

Envelopeld Stamping: Disabled

Stoke-on-Trent, Staffordshire ST4 7LQ

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Natalie.Boot@uk.lucideon.com

IP Address: 86.188.222.148

### Record Tracking

Status: Original

Holder: Natalie Boot

Location: DocuSign

28-Apr-25 | 12:40

Natalie.Boot@uk.lucideon.com

### Signer Events

### Signature

### Timestamp

Natalie Boot

natalie.boot@uk.lucideon.com

Admin Supervisor Placeholder

Lucideon Limited

Security Level: Email, Account Authentication  
(Required), Authentication, Login with SSO

*Natalie Boot*

Signature Adoption: Pre-selected Style

Signature ID:

90369E90-4813-4123-B65D-5E8FBD375BF3

Using IP Address: 86.188.222.148

Sent: 28-Apr-25 | 12:40

Viewed: 28-Apr-25 | 12:40

Signed: 28-Apr-25 | 12:41

With Signing Authentication via Docusign password

With Signing Reasons (on each tab):

I have reviewed this document

I have reviewed this document

I have reviewed this document

Electronic Record and Signature Disclosure:

Not Offered via Docusign

### In Person Signer Events

### Signature

### Timestamp

### Editor Delivery Events

### Status

### Timestamp

### Agent Delivery Events

### Status

### Timestamp

### Intermediary Delivery Events

### Status

### Timestamp

### Certified Delivery Events

### Status

### Timestamp

### Carbon Copy Events

### Status

### Timestamp

### Witness Events

### Signature

### Timestamp

### Notary Events

### Signature

### Timestamp

### Envelope Summary Events

### Status

### Timestamps

Envelope Sent

Hashed/Encrypted

28-Apr-25 | 12:40

Certified Delivered

Security Checked

28-Apr-25 | 12:40

Signing Complete

Security Checked

28-Apr-25 | 12:41

Completed

Security Checked

28-Apr-25 | 12:41

### Payment Events

### Status

### Timestamps