



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 31 January 2025

<b>Product Name</b>	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
<b>Product Code</b>	7514852		
<b>Batch Number</b>	FMP25031	61008	
<b>Production Date</b>	31/01/2025		
<b>Expiration Date</b>	EXP 31/01/2027		

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	11.7
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide		100	180	138.375

On behalf of Diversey site Quality Manger	Name:	Natalia Traichel    Angelika Pietraszko
	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: 05 February 2025

<b>Product Name</b>	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
<b>Product Code</b>	7514852		
<b>Batch Number</b>	FMP25031	61008	
<b>Production Date</b>	31/01/2025		
<b>Expiration Date</b>	EXP 31/01/2027		

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manger	<b>Name:</b>	Edyta Rodrigues    Angelika Pietraszko
	<b>Position</b>	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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# STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-50869A

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<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	61011	8	Case

Validation Reference Number: 5857

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Processing Run Start Date 05-Oct-2024 6:00 PM

Processing Run End Date 06-Oct-2024 1:43 AM

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Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	30.6
Reference Dose Range (kGy)	26.1 - 35.8	Calculated Max Dose (kGy)	35.8

---

PO Number: 409112

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

**Gamma Process Run Approval authorized by STERIS**

DateTime Esigned 06-Oct-2024 3:17 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 WO61011 will be used in finished batch FMP25031 61008.

*Olga Kirchner*

# PHARMACEUTICAL ANALYSIS REPORT

**Flexible Medical Packaging**  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

This report supersedes the report  
dated 06 March 2025 Ref: N25624 - 1  
**Sterility Testing.**

FAO: Mrs. Olga Kirchner

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

**Sample Description:** Sample Code: Fmp25031 61008

**Lucideon Sample Number:** N25624 - 1

**Lucideon Report Number:** N25624 - 1/MFEP

**Issue Number:** 2

**Date Logged:** 11-Feb-2025

**Order Number:** 409991

**Date Reported:** 12-Mar-2025

**Date(s) of Test(s):** 12-Feb-2025 to 02-Mar-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: 12 March 2025 | 16:27 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

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# PHARMACEUTICAL ANALYSIS REPORT

**Flexible Medical Packaging**  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

This report supersedes the report  
dated 06 March 2025 Ref: N25624 - 2  
**Sterility Testing.**

FAO: Mrs. Olga Kirchner

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

**Sample Description:** Sample Code: Fmp25031 61008

**Lucideon Sample Number:** N25624 - 2

**Lucideon Report Number:** N25624 - 2/MFEP

**Issue Number:** 2

**Date Logged:** 11-Feb-2025

**Order Number:** 409991

**Date Reported:** 12-Mar-2025

**Date(s) of Test(s):** 13-Feb-2025 to 03-Mar-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: 12 March 2025 | 16:28 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

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## Certificate Of Completion

Envelope Id: 646820F3-B862-4DFF-AC61-A1739A419F93  
 Subject: Complete with Docusign: N25624 - 1 FMP.pdf, N25624 - 2 FMP.pdf  
 Source Envelope:  
 Document Pages: 2  
 Certificate Pages: 1  
 AutoNav: Enabled  
 Envelopeld Stamping: Disabled  
 Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Status: Completed  
 Envelope Originator:  
 Natalie Boot  
 Queens Road  
 Stoke-on-Trent, Staffordshire ST4 7LQ  
 Natalie.Boot@uk.lucideon.com  
 IP Address: 86.188.245.148

## Record Tracking

Status: Original  
 12-Mar-25 | 16:26  
 Holder: Natalie Boot  
 Natalie.Boot@uk.lucideon.com  
 Location: DocuSign

## Signer Events

Natalie Boot  
 natalie.boot@uk.lucideon.com  
 Admin Supervisor Placeholder  
 Lucideon Limited  
 Security Level: Email, Account Authentication (Required), Authentication, Login with SSO

## Signature

*Natalie Boot*  
 Signature Adoption: Pre-selected Style  
 Signature ID:  
 90369E90-4813-4123-B65D-5E8FBD375BF3  
 Using IP Address: 86.188.245.148  
 With Signing Authentication via Docusign password  
 With Signing Reasons (on each tab):  
 I have reviewed this document  
 I have reviewed this document

## Timestamp

Sent: 12-Mar-25 | 16:27  
 Viewed: 12-Mar-25 | 16:27  
 Signed: 12-Mar-25 | 16:28

**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

Event	Status	Timestamp
Envelope Sent	Hashed/Encrypted	12-Mar-25   16:27
Certified Delivered	Security Checked	12-Mar-25   16:27
Signing Complete	Security Checked	12-Mar-25   16:28
Completed	Security Checked	12-Mar-25   16:28

## Payment Events

## Status

## Timestamps