



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 25 February 2025

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP25056	61457	
Production Date	25/02/2025		
Expiration Date	EXP 25/02/2027		

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	11.8
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	Edyta Rodrigues
	Position	Quality Control Inspector	

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

Date: 25 February 2025

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP25056	61457	
Production Date	25/02/2025		
Expiration Date	EXP 25/02/2027		

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	1.7
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Edyta Rodrigues
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-53260A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	61460 - STR001313	8	Case

Validation Reference Number: 5857

Processing Run Start Date 16-Jan-2025 6:07 PM

Processing Run End Date 17-Jan-2025 12:08 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	31.0
Reference Dose Range (kGy)	26.1 - 35.8	Calculated Max Dose (kGy)	36.4

PO Number: 409772

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jan-2025 7:06 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 WO61460 will be used in finished batch Fmp25056 61457.

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 Base

Sample Description: Sample Code: Fmp25056 61457

Lucideon Sample Number: N25967 - 1

Lucideon Report Number: N25967 - 1/MFEP

Issue Number: 1

Date Logged: 04-Mar-2025

Order Number: 410175

Date Reported: 21-Mar-2025

Date(s) of Test(s): 06-Mar-2025 to 20-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:

Tracy Wheeler

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 21 March 2025 | 15:03 GMT

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

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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Stone Business Park query@lucideon.com
Brooms Road, Stone www.lucideon.com
Staffordshire, ST15 0SH, UK 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 Activator

Sample Description: Sample Code: Fmp25056 61457

Lucideon Sample Number: N25967 - 2

Lucideon Report Number: N25967 - 2/MFEP

Issue Number: 1

Date Logged: 04-Mar-2025

Order Number: 410175

Date Reported: 21-Mar-2025

Date(s) of Test(s): 06-Mar-2025 to 20-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:

Tracy Wheeler

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 21 March 2025 | 15:03 GMT

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Tracy Wheeler

Business Support Administrator

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Stone Business Park query@lucideon.com
Brooms Road, Stone www.lucideon.com
Staffordshire, ST15 0SH, UK Reg. England 1960455

Certificate Of Completion

Envelope Id: 537052B8-B60A-4637-BFBF-6B37E7026631

Status: Completed

Subject: N25967 - 1 Flexible Medical

Source Envelope:

Document Pages: 2

Signatures: 2

Envelope Originator:

Certificate Pages: 1

Initials: 0

Tracy Wheeler

AutoNav: Enabled

Queens Road

Envelopeld Stamping: Disabled

Stoke-on-Trent, Staffordshire ST4 7LQ

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

Tracy.Wheeler@uk.lucideon.com

IP Address: 86.188.222.148

Record Tracking

Status: Original

Holder: Tracy Wheeler

Location: DocuSign

21-Mar-25 | 14:59

Tracy.Wheeler@uk.lucideon.com

Signer Events

Signature

Timestamp

Tracy Wheeler

Sent: 21-Mar-25 | 15:02

tracy.wheeler@uk.lucideon.com

Viewed: 21-Mar-25 | 15:03

Placeholder

Signed: 21-Mar-25 | 15:03

Lucideon Limited

Signature Adoption: Pre-selected Style

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

Signature ID:

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Using IP Address: 86.188.222.148

With Signing Authentication via Docusign password

With Signing Reasons (on each tab):

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

21-Mar-25 | 15:02

Certified Delivered

Security Checked

21-Mar-25 | 15:03

Signing Complete

Security Checked

21-Mar-25 | 15:03

Completed

Security Checked

21-Mar-25 | 15:03

Payment Events

Status

Timestamps