



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 10 April 2025

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP25099	61927	
Production Date	09/04/2025		
Expiration Date	EXP 09/04/2027		

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	1.007
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
--------------	--------------	-----------------------------------



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 14 April 2025

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP25099	61927	
Production Date	09/04/2025		
Expiration Date	EXP 09/04/2027		

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	1.020

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
--------------	--------------	-----------------------------------

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: Fmp25099 61927

Lucideon Sample Number: N251730 - 1

Lucideon Report Number: N251730 - 1/MFEP

Issue Number: 1

Date Logged: 24-Apr-2025

Order Number: 410500

Date Reported: 19-May-2025

Date(s) of Test(s): 27-Apr-2025 to 11-May-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: 19 May 2025 | 15:37 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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

Lucideon Limited
Stone Business Park
Brooms Road, Stone
Staffordshire, ST15 0SH, UK
T +44 (0)1785 331874
query@lucideon.com
www.lucideon.com
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: Fmp25099 61927

Lucideon Sample Number: N251730 - 2

Lucideon Report Number: N251730 - 2/MFEP

Issue Number: 1

Date Logged: 24-Apr-2025

Order Number: 410500

Date Reported: 19-May-2025

Date(s) of Test(s): 27-Apr-2025 to 11-May-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: 19 May 2025 | 15:38 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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

Lucideon Limited
Stone Business Park
Brooms Road, Stone
Staffordshire, ST15 0SH, UK
T +44 (0)1785 331874
query@lucideon.com
www.lucideon.com
Reg. England 1960455

Certificate Of Completion

Envelope Id: 880C4325-ED16-4D9F-B347-5ECD6AAA2C72

Status: Completed

Subject: N251904

Source Envelope:

Document Pages: 2

Signatures: 2

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: 86.188.245.148

Record Tracking

Status: Original

Holder: Natalie Boot

Location: DocuSign

19-May-25 | 15:36

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: 86.188.245.148

Sent: 19-May-25 | 15:37

Viewed: 19-May-25 | 15:37

Signed: 19-May-25 | 15:38

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

19-May-25 | 15:37

Certified Delivered

Security Checked

19-May-25 | 15:37

Signing Complete

Security Checked

19-May-25 | 15:38

Completed

Security Checked

19-May-25 | 15:38

Payment Events

Status

Timestamps

STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)
Gamma Process Run ID 2173-54851A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	61928- STR001313	8	Case
Validation Reference Number: 5857			

Processing Run Start Date 14-Mar-2025 6:08 PM
Processing Run End Date 15-Mar-2025 12:10 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)	37.5

PO Number: 410228

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

Gamma Process Run Approval authorized by STERIS
DateTime Esigned 15-Mar-2025 3:04 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 WO61928 will be used in finished batch Fmp25099 61927 .

Olga Kirchner