



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 09 November 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP23313	58892	
Production Date	09/11/2023		
Expiration Date	EXP 09/11/2025		

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	11.4
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide	PAG N°299	100	180	135

On behalf of Diversey site Quality Manger	Name:	Natlia Traichel Justyna Staron
	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: 09 November 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP23313	58892	
Production Date	09/11/2023		
Expiration Date	EXP 09/11/2025		

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	1.017

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

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)
Gamma Process Run ID 2173-41553A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	58913	15	Case
Validation Reference Number: 5857			

Processing Run Start Date: 21-Oct-2023 6:49 AM

Processing Run End Date: 21-Oct-2023 12:33 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.3
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	32.8

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: 406578

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

Gamma Process Run Approval authorized by STERIS

Date/Time: 21-Oct-2023 2:50 PM

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 WO58913 will be used in finished batch Fmp23313 58892.

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: Fmp23313 58892

Lucideon Sample Number: UK234252-32022

Lucideon Report Number: UK234252-32022/MFEP **Issue Number:** 1

Date Logged: 20-Nov-2023 **Order Number:** 406883

Date Reported: 11-Dec-2023 **Date(s) of Test(s):** 23-Nov-2023 to 07-Dec-2023

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

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 11 December 2023 | 14:55 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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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: Fmp23313 58892

Lucideon Sample Number: UK234252-32023

Lucideon Report Number: UK234252-32023/MFEP **Issue Number:** 1

Date Logged: 20-Nov-2023 **Order Number:** 406883

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Sterility Testing
Membrane Filtration EP

Test Results:

Result: Pass

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DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 11 December 2023 | 14:55 GMT

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Mrs Natalie Boot

Senior Business Support Administrator

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