



Diversey Europe Operations BV
MaarssenbroeksdiJK 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 01 December 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP22335	55396	
Production Date	01/12/2022		
Expiration Date	EXP 01/12/2024		

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	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide		100	180	141.75

On behalf of Diversey site Quality Manger	Name:	Wrszula Haraburda Edyta Rodrigues
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24th 2017
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CERTIFICATE OF ANALYSIS

Date: 03 December 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP22335	55396	
Production Date	01/12/2022		
Expiration Date	EXP 01/12/2024		

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:	Edyta Rodrigues Urszula Haraburda
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)
Gamma Process Run ID 2173-32295A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	55424	16	Case
Validation Reference Number: 5857			

Processing Run Start Date: 31-Oct-2022 7:25 AM

Processing Run End Date: 31-Oct-2022 2:05 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.3
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	34.7

PO Number: 403728

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 31-Oct-2022 7:18 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 WO55424 will be used in finished batch Fmp22335 55396

Olga Kirchner

Document ID: 126496

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: Fmp22335 55396

Lucideon Sample Number: UK224882-31881

Lucideon Report Number: UK224882-31881/MFEP **Issue Number:** 1

Date Logged: 13-Dec-2022 **Order Number:** 404148

Date Reported: 23-Jan-2023 **Date(s) of Test(s):** 05-Jan-2023 to 19-Jan-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

NcBook 23 JAN 23

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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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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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: Fmp22335 55396

Lucideon Sample Number: UK224882-31882

Lucideon Report Number: UK224882-31882/MFEP **Issue Number:** 1

Date Logged: 13-Dec-2022 **Order Number:** 404148

Date Reported: 23-Jan-2023 **Date(s) of Test(s):** 05-Jan-2023 to 19-Jan-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

UCBAOK 23 JAN 23

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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