



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
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CERTIFICATE OF ANALYSIS

Date: 14 February 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP23045	57269	
Production Date	14/02/2023		
Expiration Date	EXP 14/02/2025		

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	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.017

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Edyta Rodrigues
	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: 15 February 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP23045	57269	
Production Date	14/02/2023		
Expiration Date	EXP 14/02/2025		

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	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide		100	180	124.875

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrigues 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 2173-33390A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	55368	37	Case
Validation Reference Number: 5857			

Processing Run Start Date: 10-Dec-2022 1:24 PM

Processing Run End Date: 10-Dec-2022 9:04 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.9
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	35.4

PO Number: 404108

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 11-Dec-2022 7:13 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 WO55368 will be used in finished batch Fmp23045 57269.

Olga Kirchner

Document ID: 130215

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: Fmp23045 57269

Lucideon Sample Number: UK23639-4284

Lucideon Report Number: UK23639-4284/MFEP

Issue Number: 1

Date Logged: 21-Feb-2023

Order Number: 404616

Date Reported: 15-Mar-2023

Date(s) of Test(s): 01-Mar-2023 to 15-Mar-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



15 Mar 23.

Robin Williams

Microbiology Laboratory Supervisor

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.

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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: Fmp23045 57269

Lucideon Sample Number: UK23639-4285

Lucideon Report Number: UK23639-4285/MFEP

Issue Number: 1

Date Logged: 21-Feb-2023

Order Number: 404616

Date Reported: 15-Mar-2023

Date(s) of Test(s): 01-Mar-2023 to 15-Mar-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



15 Mar 23

Robin Williams

Microbiology Laboratory Supervisor

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