



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 07 March 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP23066	57407	
Production Date	07/03/2023		
Expiration Date	EXP 07/03/2025		

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.017

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrigues Urszula Haraburda
	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: 07 March 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP23066	57407	
Production Date	07/03/2023		
Expiration Date	EXP 07/03/2025		

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	11.45
Specific Gravity (20°C)	DM004	1.004	1.020	1.009
Potential Chlorine Dioxide		100	180	135

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

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-34939A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	56310	31	Case
Validation Reference Number: 5857			

Processing Run Start Date: 11-Feb-2023 7:33 PM

Processing Run End Date: 12-Feb-2023 1:30 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.6
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	34.3

PO Number: 404534

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 12-Feb-2023 8:16 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 WO56310 will be used in finished batch Fmp23066 57407.

Olga Kirchner

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: Fmp23066 57407

Lucideon Sample Number: UK23926-6197

Lucideon Report Number: UK23926-6197/MFEP

Issue Number: 1

Date Logged: 13-Mar-2023

Order Number: 404803

Date Reported: 03-Apr-2023

Date(s) of Test(s): 16-Mar-2023 to 30-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

Natalie Boot 03 APR 23

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
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

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: Fmp23066 57407

Lucideon Sample Number: UK23926-6198

Lucideon Report Number: UK23926-6198/MFEP

Issue Number: 1

Date Logged: 13-Mar-2023

Order Number: 404803

Date Reported: 03-Apr-2023

Date(s) of Test(s): 16-Mar-2023 to 30-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

Natalie Boot 03 Apr 23

Mrs Natalie Boot

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