Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 19 April 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP23109 56713
Production Date	19/04/2023
Expiration Date	EXP 19/04/2025

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 Lower - Upper**		**Results**
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	1.005
Potential Chlorine Dioxide		100	180	135

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrigues Justyna Staron
	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: 19 April 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP23109 56713
Production Date	19/04/2023
Expiration Date	EXP 19/04/2025

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 Lower - Upper**		**Results**
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	1.5	2.5	2.0
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Edyta Rodrigues
	Position	Quality Control Inspector

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COA Template	*Version : 04*	*Date of issuing : March 11th 2019*

STERIS: Gamma Certificate Of Processing

Prepared for: **FLEXIBLE MEDICAL PACKAGING LTD (8245)**

Gamma Process Run ID **2173-35886A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**56741**	**8**	**Case**

Validation Reference Number: 5857

Processing Run Start Date: 17-Mar-2023 4:14 AM

Processing Run End Date: 17-Mar-2023 10:10 AM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**30.0**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**35.8**

PO Number: 404819

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 17-Mar-2023 12:38 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 WO56741 will be used in finished batch Fmp23109 56713.

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: Fmp23109 56713

Lucideon Sample Number: UK231470-10037

Lucideon Report Number: UK231470-10037/MFEP **Issue Number:** 1

Date Logged: 24-Apr-2023 **Order Number:** 405102

Date Reported: 16-May-2023 **Date(s) of Test(s):** 28-Apr-2023 **to** 12-May-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:
Tracy Wheeler
Signer Name: Tracy Wheeler
Signing Reason: I have reviewed this document
Signing Time: 16 May 2023 | 11:10 BST
D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler
Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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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: Fmp23109 56713		
Lucideon Sample Number:	UK231470-10038		
Lucideon Report Number:	UK231470-10038/MFEP	**Issue Number:**	1
Date Logged:	24-Apr-2023	**Order Number:**	405102
Date Reported:	16-May-2023	**Date(s) of Test(s):**	28-Apr-2023 **to** 12-May-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:
Tracy Wheeler
Signer Name: Tracy Wheeler
Signing Reason: I have reviewed this document
Signing Time: 16 May 2023 | 11:10 BST
D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler
Business Support Administrator

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