Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 29 September 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP23264 58410
Production Date	21/09/2023
Expiration Date	EXP 21/09/2025

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	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide	DM020	100	180	151.875

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrigues Angelika Pietraszko
	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: 29 September 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP23264 58410
Production Date	21/09/2023
Expiration Date	EXP 21/09/2025

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:	Edyta Rodrigues Angelika Pietraszko
	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 **2173-40175A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**58431**	**8**	**Case**

Validation Reference Number: 5857

Processing Run Start Date: 01-Sep-2023 9:42 PM

Processing Run End Date: 02-Sep-2023 3:51 AM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**31.9**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**37.9**

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

PO Number: 406188

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

Gamma Process Run Approval authorized by STERIS

Date/Time: 04-Sep-2023 3:15 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

Item irradiated under WO58431 will be used in finished batch Fmp23264 58410.

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: Fmp23264 58410

Lucideon Sample Number: UK233613-27575

Lucideon Report Number: UK233613-27575/MFEP **Issue Number:** 1

Date Logged: 02-Oct-2023 **Order Number:** 406413

Date Reported: 23-Oct-2023 **Date(s) of Test(s):** 03-Oct-2023 **to** 17-Oct-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: 23 October 2023 | 12:44 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot
Senior Business Support Administrator

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

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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: Fmp23264 58410

Lucideon Sample Number: UK233613-27576

Lucideon Report Number: UK233613-27576/MFEP **Issue Number:** 1

Date Logged: 02-Oct-2023 **Order Number:** 406413

Date Reported: 23-Oct-2023 **Date(s) of Test(s):** 03-Oct-2023 **to** 21-Oct-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: 23 October 2023 | 12:45 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot
Senior Business Support Administrator

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

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

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Natalie Boot
Queens Road
Stoke-on-Trent, Staffordshire ST4 7LQ
Natalie.Boot@uk.lucideon.com
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Natalie.Boot@uk.lucideon.com

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Signing Complete	Security Checked	23-Oct-23 | 12:45
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