Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

Date: 04 May 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off
Product Code	7514852
Batch Number	FMP22124 53161
Production Date	04/05/2022
Expiration Date	EXP 04/05/2024

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 Lower**	**- Upper**	**Results**
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	9.0	12.5	12.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide		100	180	135

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template *Version : 02* *Date of issuing : November 24th 2017*

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CERTIFICATE OF ANALYSIS

Date: 04 May 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7514852
Batch Number	FMP22124 53161
Production Date	04/05/2022
Expiration Date	EXP 04/05/2024

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 Lower - Upper**		**Results**
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	1.018

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

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COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

STERIS: Gamma Certificate Of Processing

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

Gamma Process Run ID **2173-27516A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**53412**	**8**	**Case**

Validation Reference Number: 5857

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**29.4**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**38.1**

PO Number: 401363

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 16-Apr-2022 12:06 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 WO53412 will be used in finished batch FMP22124 53161.

Olga Kirchner

Document ID: 109031

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: Fmp22124 53161		
Lucideon Sample Number:	UK221980-12789		
Lucideon Report Number:	UK221980-12789/MFEP	**Issue Number:**	1
Date Logged:	12-May-2022	**Order Number:**	402551
Date Reported:	06-Jun-2022	**Date(s) of Test(s):**	17-May-2022 **to** 31-May-2022

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

NcBoot 06-JUN-22

Mrs Natalie Boot
Senior Business Support Administrator

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

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Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on:	Bi-Spore Base		
Sample Description:	Sample Code: Fmp22124 53161		
Lucideon Sample Number:	UK221980-12790		
Lucideon Report Number:	UK221980-12790/MFEP	**Issue Number:**	1
Date Logged:	12-May-2022	**Order Number:**	402551
Date Reported:	06-Jun-2022	**Date(s) of Test(s):**	17-May-2022 **to** 31-May-2022

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

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