

First off



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CERTIFICATE OF ANALYSIS

Date: 03.02.2020

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 20034, 49138
Production Date	03.02.2020
Expiration Date	EXP 03/02/2022

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	11.4
Specific Gravity (20°C)	DM004	1.004	1.020	1.012
Potential Chlorine Dioxide (ppm)		100	180	121.5 ppm

On behalf of Diversey site Quality Manager	Name :	J. Staan, A. Bomp
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
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CERTIFICATE OF ANALYSIS

Date: 03.02.2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 20034, 49138
Production Date	03.02.2020
Expiration Date	EXP 02/2022

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	2.1
Specific Gravity (20°C)	DM004	1.010	1.030	1.024

On behalf of Diversey site Quality Manager	Name :	J. Staan, A. Bony
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-7354A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO49137	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 10-Jan-20 04:40 PM

Processing Run End Date: 11-Jan-20 01:18 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.3
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.1

PO Number: PO34552 MOC APPLIES TO THIS ORDER

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

Signature Manifest

Reviewed and E-Signed By: **Bhavya Ramisetty (Quality Engineer)**

Date/Time E-Signed: 2020-01-23 08:28 AM

Document Content Revision: 1

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 WO49137 will be used in finished batch Fmp20034 49138.

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: Fmp20034 49138

Lucideon Sample Number: UK20745-5570

Lucideon Report Number: UK20745-5570/MFEP

Issue Number: 1

Date Logged: 13-Feb-2020

Order Number: PO 34767

Date Reported: 05-Mar-2020

Date(s) of Test(s): 18-Feb-2020 to 03-Mar-2020

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 05-Mar-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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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: Fmp20034 49138

Lucideon Sample Number: UK20745-5571

Lucideon Report Number: UK20745-5571/MFEP

Issue Number: 1

Date Logged: 13-Feb-2020

Order Number: PO 34767

Date Reported: 05-Mar-2020

Date(s) of Test(s): 18-Feb-2020 to 03-Mar-2020

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 05-Mar-20

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