



CERTIFICATE OF ANALYSIS

Date: 21.12.2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP20356, 50356
Production Date	21.12.2020
Expiration Date	EXP 21/12/2022

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	<i>[Signature]</i>
	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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Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 21.12.2020

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 20356, 50956
Production Date	21.12.2020
Expiration Date	EXP 21/12/2022

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	1.005
Potential Chlorine Dioxide (ppm)		100	180	172.125 ppm

On behalf of Diversey site Quality Manager	Name :	J. van der Pijl
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of Issuing : November 24 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15433A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO50957	8	Case
Validation Reference Number: 4725			

Processing Run Start Date: 04-Dec-20 01:30 AM

Processing Run End Date: 04-Dec-20 06:52 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.6
Reference Dose Range (kGy):	30.2 - 39.2	Calculated Max Dose (kGy):	33.9

PO Number: 36894

Gamma Process Run Approval authorized by STERIS

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 WO50957 will be used in finished product Fmp20356 50956.

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: Fmp20356 50956

Lucideon Sample Number: UK2166-607

Lucideon Report Number: UK2166-607/MFEP

Issue Number: 1

Date Logged: 08-Jan-2021

Order Number: PO 37156

Date Reported: 19-Feb-2021

Date(s) of Test(s): 30-Jan-2021 to 19-Feb-2021

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 19-Feb-21

Mrs Natalie Boot

Business Support Administrator

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: Fmp20356 50956

Lucideon Sample Number: UK2166-608

Lucideon Report Number: UK2166-608/MFEP

Issue Number: 1

Date Logged: 08-Jan-2021

Order Number: PO 37156

Date Reported: 19-Feb-2021

Date(s) of Test(s): 30-Jan-2021 to 13-Feb-2021

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 19-Feb-21

Mrs Natalie Boot

Business Support Administrator

Page 1 of 1

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