



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 04.11.2019

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP19308, 48214
Production Date	04.11.2019
Expiration Date	EXP 04/11/2021

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	11.8
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	145.125

On behalf of Diversey site Quality Manager	Name :	J. Staver Poutyuslo
	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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First off



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CERTIFICATE OF ANALYSIS

Date: 05.11.2019

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP19308, 48214
Production Date	04.11.2019
Expiration Date	EXP 04/11/2021

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	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	J. Staven Partgus
	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: 2173-5505A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO48215	8	Case
Validation Reference Number: 4725			

Processing Run Start Date: 09-Oct-19 01:18 PM

Processing Run End Date: 09-Oct-19 07:39 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.1
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.2

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 WO48215 will be used in finished batch FMP19308 48214.

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT



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: Fmp19308 48214

Lucideon Sample Number: (196202)-47208

Lucideon Report Number: (196202)-47208/MFEP

Issue Number: 1

Date Logged: 12-Nov-2019

Order Number: 34274

Date Reported: 10-Dec-2019

Date(s) of Test(s): 26-Nov-2019 to 10-Dec-2019

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 10-Dec-19

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.

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

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 Base

Sample Description: Sample Code: Fmp19308 48214

Lucideon Sample Number: (196202)-47209

Lucideon Report Number: (196202)-47209/MFEP

Issue Number: 1

Date Logged: 12-Nov-2019

Order Number: 34274

Date Reported: 10-Dec-2019

Date(s) of Test(s): 26-Nov-2019 to 10-Dec-2019

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 10-Dec-19

Mrs Natalie Boot

Senior Business Support Assistant

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