

FIRST OFF



Diversey Europe Operations BV
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The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 19/06/2020

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP20169, 49667
Production Date	17/06/2020
Expiration Date	EXP 17/06/2022

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	11.6
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	138.375 ppm

On behalf of Diversey site Quality Manager	Name :	
	Position	

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

Date: 19/06/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 20169 49667
Production Date	17/06/2020
Expiration Date	Exp. 17/06/2022

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	1.3
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	Pantjules, Marahide
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10785A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO49666	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 24-May-20 03:09 PM

Processing Run End Date: 24-May-20 09:02 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	25.4
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	33.4

PO Number: 35521

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 WO49667 will be used in finished batch Fmp20169 49667.

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: Fmp20169 49667

Lucideon Sample Number: UK202591-18863

Lucideon Report Number: UK202591-18863/MFEP **Issue Number:** 1

Date Logged: 24-Jun-2020 **Order Number:** PO 35764

Date Reported: 15-Jul-2020 **Date(s) of Test(s):** 02-Jul-2020 to 15-Jul-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



15 JUL 20

Mrs Andrea Saunders

Business Support Assistant

Page 1 of 1

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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: Fmp20169 49667

Lucideon Sample Number: UK202591-18864

Lucideon Report Number: UK202591-18864/MFEP **Issue Number:** 1

Date Logged: 24-Jun-2020 **Order Number:** PO 35764

Date Reported: 15-Jul-2020 **Date(s) of Test(s):** 02-Jul-2020 to 15-Jul-2020

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