

Diversey Europe Operations BV Maarssenbroeksedlijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 17/05/2021

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP21137; 51715
Production Date	17/05/2021
Expiration Date	EXP 17/05/2023

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	_	nits - Upper	Results
Appearance	Visual	Clear Colourless Liquid		d Clear Colourless
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	158.625

On behalf of Diversey site Quality Manager	Name:	J.Staron A.Partynska
	Position	Quality Control Inspector

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

Date: 17/05/2021

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP21137; 51715
Production Date	17/05/2021
Expiration Date	EXP17/05/2023

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	_	nits Upper	Results
Appearance	Visual	Clear Colou	rless Liquid	Clear Colourless Liquid
pH (neat solution)	DM001	1.5	2.5	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name:	J.Staron A.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: 2173-18774A

Product CodeLot NumberQuantityUOMBI-SP B3 COMPONENTS DV4725WO517148Case

Validation Reference Number: 4725

Processing Run Start Date: 28-Apr-21 10:00 PM

Processing Run End Date: 29-Apr-21 03:48 AM

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): 34.1

PO Number: 37882

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

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 WO51714 will be used in finished batch FMP21137 51715.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 77407

Last Revised in Rel 2.0.0.0

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PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Bi-Spore Activator

Sample Description:

Sample Code: Fmp21137 51715

Lucideon Sample Number: UK212308-15885

Lucideon Report Number: UK212308-15885/MFEP

Issue Number:

Date Logged:

27-May-2021

Order Number:

PO 38156

Date Reported:

17-Jun-2021

Date(s) of Test(s):

01-Jun-2021 to 15-Jun-2021

Sterility Testing

Membrane Filtration EP

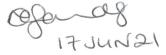
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



Mrs Andrea Saunders

Business Support Administrator

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 Base

Sample Description:

Sample Code: Fmp21137 51715

Lucideon Sample Number: UK212308-15886

Lucideon Report Number: UK212308-15886/MFEP

Issue Number:

Date Logged:

27-May-2021

Order Number:

PO 38156

Date Reported:

17-Jun-2021

Date(s) of Test(s):

01-Jun-2021 to 15-Jun-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



Mrs Andrea Saunders

Business Support Administrator