

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date:

07 July 2023

Product Name	CLEARKLENS BI-SP	ORE ACTIVATOR SOLUTION VH26 first off
Product Code	7515828	
Batch Number	FMP23188	57785
Production Date	07/07/2023	
Expiration Date	EXP 07/07/2025	

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	Limi Lower	ts - Upper	Results
Appearance	Visual	Clear Colou	ırless Liquid	Clear Colourless Liquid
pH (neat solution)	DM001	9.0	12.5	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide		100	180	141.75

On behalf of Diversey site	Name:	Justyna Staron Ewelína Nowaczyk
Quality Manger	Position	Quality Control Inspector

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The decention being is		
COA Template	Version : 04	Date of issuing : March 11th 2019



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CERTIFICATE OF ANALYSIS

Date:

07 July 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP23188 57785
Production Date	07/07/2023
Expiration Date	EXP 07/07/2025

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	Limit Lower	ts - Upper	Results
Appearance	Visual	Clear Colour	rless Liquid	Clear Colourless Liquid
pH (neat solution)	DM001	1.5	2.5	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site	Name:	Justyna Staron Ewelína Nowaczyk
Quality Manger	Position	Quality Control Inspector

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COA Template	Version : 04	Date of issuing : March 11th 2019

STERIS: Gamma Certificate Of Processing

Gamma Process Run ID 2173-3829	7A	NG LID (0243)	
Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	57788	8	Case
Validation Reference Number:	5857		
Processing Run Start Date: 24-Jun-202	23 4:45 AM		
Processing Run End Date: 24-Jun-202	23 10:44 AM		
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.6
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	36.3

ELEXIBLE MEDICAL PACKAGING LTD (8245)

PO Number: 405585

Prenared for

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 24-Jun-2023 5:44 PM

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 WO57788 will be used in finished batch Fmp23188 57785.

Olga Kirchner

Document ID: 147684

N/A

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: Fmp23188 57785 Lucideon Sample Number: UK232683-20443 Lucideon Report Number: UK232683-20443/MFEP Issue Number: 1 **Order Number:** Date Logged: 13-Jul-2023 405791 Date(s) of Test(s): 19-Jul-2023 07-Aug-2023 **Date Reported:**

Sterility Testing Membrane Filtration EP to 02-Aug-2023

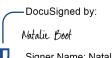
Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report



Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 07 August 2023 | 15:45 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior 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



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: Fmp23188 57785 Lucideon Sample Number: UK232683-20444 Lucideon Report Number: UK232683-20444/MFEP Issue Number: 1 Date Logged: 13-Jul-2023 Order Number: 405791 Date(s) of Test(s): 19-Jul-2023 07-Aug-2023 to 02-Aug-2023 **Date Reported: 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



Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 07 August 2023 | 15:45 BST

Mrs Natalie Boot

Senior Business Support Administrator

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