



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 26 August 2022

| | | | |
|-----------------|---|-------|--|
| Product Name | CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off | | |
| Product Code | 7514852 | | |
| Batch Number | FMP22238 | 54898 | |
| Production Date | 26/08/2022 | | |
| Expiration Date | EXP 26/08/2024 | | |

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 | 10.5 |
| Specific Gravity (20°C) | DM004 | 1.004 | 1.020 | 1.005 |
| Potential Chlorine Dioxide | | 100 | 180 | 158.625 |

| | | |
|--|----------|---------------------------------------|
| On behalf of Diversey site Quality Manger | Name: | Justyna Staron Urszula Haraburda |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|--------------|--------------|--------------------------------------|
| COA Template | Version : 02 | Date of issuing : November 24th 2017 |
|--------------|--------------|--------------------------------------|



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CERTIFICATE OF ANALYSIS

Date: 26 August 2022

| | | | |
|-----------------|--|-------|--|
| Product Name | CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off | | |
| Product Code | 7514852 | | |
| Batch Number | FMP22238 | 54898 | |
| Production Date | 26/08/2022 | | |
| Expiration Date | EXP 26/08/2024 | | |

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 | 1.7 |
| Specific Gravity (20°C) | DM004 | 1.010 | 1.030 | 1.017 |

| | | |
|--|----------|---------------------------------------|
| On behalf of Diversey site Quality Manger | Name: | Justyna Staron urszula Haraburda |
| | Position | Quality Control Inspector |

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-28924A

| <u>Product Code</u> | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-------------------|-----------------|------------|
| BI-SP B3 Components DV5857 | 54832 | 15 | Case |
| Validation Reference Number: 5857 | | | |

| | | | |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 40.0 | Calculated Min Dose (kGy): | 30.3 |
|-----------------------------|-------------|----------------------------|------|

| | | | |
|-----------------------------|-------------|----------------------------|------|
| Reference Dose Range (kGy): | 26.1 - 35.8 | Calculated Max Dose (kGy): | 35.9 |
|-----------------------------|-------------|----------------------------|------|

PO Number: 402719

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

Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 15-Jun-2022 8:36 AM

Document Content Revision: 1

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 WO54832 will be used in finished batch Fmp22238 54898.

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: Sampl Code: Fmp22238 54898

Lucideon Sample Number: UK223594-23214

Lucideon Report Number: UK223594-23214/MFEP **Issue Number:** 1

Date Logged: 08-Sep-2022 **Order Number:** 403373

Date Reported: 07-Oct-2022 **Date(s) of Test(s):** 23-Sep-2022 to 07-Oct-2022

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 on 07 Oct 22

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

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: Sampl Code: Fmp22238 54898

Lucideon Sample Number: UK223594-23215

Lucideon Report Number: UK223594-23215/MFEP **Issue Number:** 1

Date Logged: 08-Sep-2022 **Order Number:** 403373

Date Reported: 07-Oct-2022 **Date(s) of Test(s):** 23-Sep-2022 to 07-Oct-2022

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 on 08/10/22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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