Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

# CERTIFICATE OF ANALYSIS

Date: 05 September 2022

| | |
|---|---|
| **Product Name** | CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off |
| **Product Code** | 7514852 |
| **Batch Number** | FMP22248 55252 |
| **Production Date** | 05/09/2022 |
| **Expiration Date** | EXP 05/09/2024 |

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 Lower | - Upper | Results |
|---|---|---|---|---|
| Appearance | Visual | Clear Colourless Liquid | | Clear Colourless Liquid |
| pH (neat solution) | DM001 | 9.0 | 12.5 | 11.7 |
| Specific Gravity (20°C) | DM004 | 1.004 | 1.020 | 1.008 |
| Potential Chlorine Dioxide | | 100 | 180 | 135 |

| | | |
|---|---|---|
| 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: 05 September 2022

| | |
|---|---|
| **Product Name** | CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off |
| **Product Code** | 7514852 |
| **Batch Number** | FMP22248 55252 |
| **Production Date** | 05/09/2022 |
| **Expiration Date** | EXP 05/09/2024 |

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 Lower - Upper | | Results |
|---|---|---|---|---|
| Appearance | Visual | Clear Colourless Liquid | | Clear Colourless Liquid |
| pH (neat solution) | DM001 | 1.5 | 2.5 | 1.9 |
| Specific Gravity (20°C) | DM004 | 1.010 | 1.030 | 1.016 |

| | | |
|---|---|---|
| On behalf of Diversey site Quality Manger | Name: | Justyna Staron Urszula Haraburda |
| | 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** **2173-29565A**

| Product Code | Lot Number | Quantity | UOM |
|---|---|---|---|
| **BI-SP B3 Components DV5857** | **55052** | **8** | **Case** |

**Validation Reference Number:** 5857

| | | | |
|---|---|---|---|
| **Specified Dose Range (kGy):** | **25.0 - 40.0** | **Calculated Min Dose (kGy):** | **30.5** |
| **Reference Dose Range (kGy):** | **26.1 - 35.8** | **Calculated Max Dose (kGy):** | **36.5** |

PO Number: 402950

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 09-Jul-2022 1:06 AM

**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 WO55052 will be used in finished batch Fmp22248 55252.

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:** | Sample Code: Fmp22248 55252 | | |
| **Lucideon Sample Number:** | UK223627-23491 | | |
| **Lucideon Report Number:** | UK223627-23491/MFEP | **Issue Number:** | 1 |
| **Date Logged:** | 12-Sep-2022 | **Order Number:** | 403392 |
| **Date Reported:** | 07-Oct-2022 | **Date(s) of Test(s):** | 23-Sep-2022 **to** 07-Oct-2022 |

**Sterility Testing**

**Membrane Filtration EP**

**Test Results:**

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

**End of Test Report**

NCBoot 07 Oct 22

Mrs Natalie Boot
**Senior Business Support Administrator**





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

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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: Fmp22248 55252 | | |
| **Lucideon Sample Number:** | UK223627-23492 | | |
| **Lucideon Report Number:** | UK223627-23492/MFEP | **Issue Number:** | 1 |
| **Date Logged:** | 12-Sep-2022 | **Order Number:** | 403392 |
| **Date Reported:** | 07-Oct-2022 | **Date(s) of Test(s):** | 23-Sep-2022 **to** 07-Oct-2022 |

**Sterility Testing**

**Membrane Filtration EP**

**Test Results:**

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

**End of Test Report**

NCBoot 07 Oct 22

Mrs Natalie Boot
**Senior Business Support Administrator**





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