

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht, The Netherlands Tel. +31 (0)30 247 6427 www.Diversey.com Diversey - Let's live

### **CERTIFICATE OF ANALYSIS**

Date issue: 14/09/2021

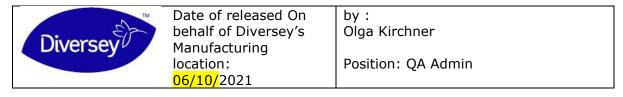
| <b>Product Name</b>    | DI ClearKlens IPA VH1 S 6x0.9L   |
|------------------------|----------------------------------|
| <b>Product Code</b>    | ⊠101105062/□101105063/□101105064 |
| <b>Batch Number</b>    | FMP21229; 52592                  |
| <b>Production date</b> | 17/08/2021                       |
| <b>Expiration Date</b> | EXP 17/08/2023                   |

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<br>Method | Specification              | Unit  | Results                 |
|-------------------------|----------------|----------------------------|-------|-------------------------|
| Appearance              | Visual         | Colourless Clear<br>Liquid | N/A   | Colourless Clear Liquid |
| Specific Gravity (20°C) | DM 004         | 0.872 - 0.883              | g/cm³ | 0.875                   |

### Control of the Sterility of the product:

| Test                              | Test Method   | Specification        | Conformity | Reference number   |
|-----------------------------------|---|----------------------|------------|--------------------|
| Sterilization                     | Gamma Irradiation   | 25.0 – 45.0<br>(kGy) | YES        | 52592              |
| Sterility<br>certificate          | Sterility by Membrane<br>Filtration<br>EP 9.0 2.6.1, USP<br>42<71> & JP XVII 4.06 | No Growth            | YES        | UK213927-<br>26499 |
| 2.6.14<br>Bacterial<br>Endotoxins | Method C – Turbidimetric<br>Kinetic Method (EP/USP<br>Criteria)                   | <0.2 EU/mL           | YES        | UK213927-<br>26500 |



The analysis results above could change over time and in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the SDS.

\*\*\*End of certificate of analysis\*\*\*

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## **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102 09/06/2021 9:15:07 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2953582 P.O.# 200705 Sales Order # 2852289

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 09/04/2021 18:39:46 GMT

| SO<br>Line # | Qty UO   | M Customer Item Number | Customer Item Description     | Customer<br>Lot Number | Customer<br>Load Number |
|--------------|----------|------------------------|-------------------------------|------------------------|-------------------------|
| 101.000      | 946 BX   | 101105062              | Diversey Clearklens IPA 900ml | FMP21229               | 52592/STR002199         |
|              | Dose Map | 302_0112               | REF: 13.5A3 AF Min = 0.717    |                        |                         |
| 102.000      | 4 BX     | 101105062_SAMPLE       | Diversey Clearklens IPA 900ml | FMP21229               | 52592/STR002199         |
|              | Dose Map | 302_0112               | REF: 13.5A3 AF Min = 0.717    |                        |                         |
|              | 950 BX   | Total                  |                               |                        |                         |

#### **Quality Test Summary**

|        |                          |                  |              |          |           | Signed By   |                         |
|--------|--------------------------|------------------|--------------|----------|-----------|-------------|-------------------------|
| Op#    | Quality Test Description | Minimum Spec     | Maximum Spec | Result   | Pass/Fail | User        | Date /Time              |
| 450.00 | Minimum Dose             | 25.0 kGy         | 45.0 kGy     | 27.0 KGY | Pass      | PSAXTON     | 09/05/2021 14:33:43 GMT |
|        |                          | Reason Code Test |              |          |           | PAUL SAXTON |                         |
| 450.00 | Maximum Dose             | 25.0 kGy         | 45.0 kGy     | 38.6 KGY | Pass      | PSAXTON     | 09/05/2021 14:34:01 GMT |
|        |                          | Reason Code Test |              |          |           | PAUL SAXTON |                         |

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: EMMA SILLS Date: 09/06/2021 09:14:56 GMT

Reason: Work Order Completions



## **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102 08/31/2021 8:21:08 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2950147 P.O.# 400650 Sales Order # 2847872

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 08/28/2021 10:59:19 GMT

| SO<br>Line # | Qty UOM  | Customer Item Number | Customer Item Description     | Customer<br>Lot Number | Customer<br>Load Number |
|--------------|----------|----------------------|-------------------------------|------------------------|-------------------------|
| 101.000      | 487 BX   | 101105062            | Diversey Clearklens IPA 900ml | FMP21214               | STR002199/52591         |
|              | Dose Map | 302_0112             | REF: 13.5A3 AF Min = 0.717    |                        |                         |
| 102.000      | 3 BX     | 101105062_SAMPLE     | Diversey Clearklens IPA 900ml | FMP21214               | STR002199/52591         |
|              | Dose Map | 302_0112             | REF: 13.5A3 AF Min = 0.717    |                        |                         |
| 103.000      | 485 BX   | 101105062            | Diversey Clearklens IPA 900ml | FMP21229               | STR002199/52592         |
|              | Dose Map | 302_0112             | REF: 13.5A3 AF Min = 0.717    |                        |                         |
|              | 975 BX   | Total                |                               |                        |                         |

#### **Quality Test Summary**

| Op#    | Quality Test Description | Minimum Spec                 | Maximum Spec | Result   | Pass/Fail | User                     | -<br>Date /Time         |
|--------|--------------------------|------------------------------|--------------|----------|-----------|--------------------------|-------------------------|
| 450.00 | Minimum Dose             | 25.0 kGy<br>Reason Code Test | 45.0 kGy     | 27.1 KGY | Pass      | JBEARNE<br>JARETH BEARNE | 08/29/2021 04:21:07 GMT |
| 450.00 | Maximum Dose             | 25.0 kGy<br>Reason Code Test | 45.0 kGy     | 38.8 KGY | Pass      | JBEARNE<br>JARETH BEARNE | 08/29/2021 04:21:29 GMT |

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: STEVEN WHELAN Date: 08/31/2021 08:16:23 GMT

Reason: Work Order Completions

### PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp21229 52592

Lucideon Sample Number: UK213927-26500

Lucideon Report Number: UK213927-26500/ETEP

Issue Number:

1

Date Logged:

15-Sep-2021

Order Number:

400844

**Date Reported:** 

24-Sep-2021

Date(s) of Test(s):

22-Sep-2021 to 22-Sep-2021

**Endotoxin Test (EP)** 

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass (<0.2000EU/ml)

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 LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp21229 52592

Lucideon Sample Number: UK213927-26499

Lucideon Report Number: UK213927-26499/MFEP

Issue Number:

Date Logged:

15-Sep-2021

Order Number:

400844

Date Reported:

06-Oct-2021

Date(s) of Test(s):

18-Sep-2021 to 02-Oct-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**