

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

### **CERTIFICATE OF ANALYSIS**

Date issue: 23 August 2023

Product Name	CLEARKLENS IPA VH1				
Product Code	<b>✓</b> 101105062	□ 101105063		101105064	
<b>Batch Number</b>	FMP23214		57852		
<b>Production Date</b>	02/08/2023				
<b>Expiration Date</b>	EXP 02/08/2025				

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	Specification		UOM	Results
Appearance	Visual	Clear Colourle	ss Liquid	NA	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872	0.883	g/cm3	0.875

### Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	57852
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK233175-24165
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK233175-24164



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 recommeded conditions indicated in the SDS.

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



## **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

08/14/2023 13:13:08 GMT

Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3395619 P.O.# 3368360

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 08/12/2023 00:57:31 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 950 вх 101105062 Diversey Clearklens IPA 900ml FMP23214 57852/STR002199 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 вх 950 Total

**Quality Test Summary** 

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	CBRITTON	08/12/2023 17:03:39 GMT
		Reason Code Test				CALLUM BRITTON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	CBRITTON	08/12/2023 17:04:05 GMT
		Reason Code Test				CALLUM BRITTON	

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: CLAIRE CICALA Date: 08/14/2023 13:10:03 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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R55480102 08/

08/21/2023 8:40:35 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3397921 P.O.# 306066 Sales Order # 3371012

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 00:00:00 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	480 BX	101105062	Diversey Clearklens IPA 900ml	FMP23214	57852/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23214	57852/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	492 BX	101105062	Diversey Clearklens IPA 900ml	FMP23223	57853/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	975 BX	Total			

#### **Quality Test Summary**

		Signed By				_	
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	38.7 KGY	Pass	DYATES DANIEL YATES	08/19/2023 12:13:31 GMT
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.4 KGY	Pass	DYATES DANIEL YATES	08/19/2023 12:13:45 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: CLAIRE CICALA Date: 08/21/2023 08:31:53 GMT

Reason: Work Order Completions

### PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23214 57852

Lucideon Sample Number: UK233175-24164

Lucideon Report Number: UK233175-24164/MFEP Issue Number: 1

Date Logged: 24-Aug-2023 Order Number: 406145

**Date Reported:** 11-Sep-2023 **Date(s) of Test(s):** 27-Aug-2023 **to** 10-Sep-2023

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** 

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 11 September 2023 | 12:08 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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Subject: Sign Source Envelope:

Document Pages: 1 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Natalie Boot

AutoNav: Enabled Queens Road

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Natalie.Boot@uk.lucideon.com IP Address: 86.188.245.148

Status: Completed

## **Record Tracking**

Status: Original Holder: Natalie Boot Location: DocuSign

11-Sep-23 | 12:07 Natalie.Boot@uk.lucideon.com

Signer Events	Signature	Timestamp			
Natalie Boot		Sent: 11-Sep-23   12:08			
natalie.boot@uk.lucideon.com	Natalie Boot	Viewed: 11-Sep-23   12:08			
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Security Level: Email, Account Authentication (Required), Authentication, Logged in	Signature Adoption: Pre-selected Style Signature ID:				
, , ,	90369E90-4813-4123-B65D-5E8FBD375BF3				
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Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	11-Sep-23   12:08
Certified Delivered	Security Checked	11-Sep-23   12:08
Signing Complete	Security Checked	11-Sep-23   12:08
Completed	Security Checked	11-Sep-23   12:08
	,	

### PHARMACEUTICAL ANALYSIS REPORT



#### Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23214 57852

Lucideon Sample Number: UK233175-24165

Lucideon Report Number: UK233175-24165/ETEP Issue Number: 1

Date Logged: 24-Aug-2023 Order Number: 406145

Date Reported: 15-Sep-2023 Date(s) of Test(s): 12-Sep-2023 to 12-Sep-2023

**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 (<0.2000 EU/ml)

Tests carried out in accordance with cGMP

Testing performed at the Brooms Road, Stone facility in compliance with GMP, pending GMP certification.

**End of Test Report** 

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 15 September 2023 | 14:08 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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# **DocuSign**

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Certificate Pages: 1 Initials: 0 Natalie Boot
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Natalie.Boot@uk.lucideon.com IP Address: 86.188.245.148

Status: Completed

**Record Tracking** 

Status: Original Holder: Natalie Boot Location: DocuSign

15-Sep-23 | 14:05 Natalie.Boot@uk.lucideon.com

Signature **Signer Events Timestamp** Natalie Boot Sent: 15-Sep-23 | 14:06 Natalie Boot natalie.boot@uk.lucideon.com Viewed: 15-Sep-23 | 14:08 PlaceHolder Signed: 15-Sep-23 | 14:08 Lucideon Limited Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required), Authentication, Logged in 90369E90-4813-4123-B65D-5E8FBD375BF3

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#### **Electronic Record and Signature Disclosure:**

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In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	15-Sep-23   14:06
Certified Delivered	Security Checked	15-Sep-23   14:08
Signing Complete	Security Checked	15-Sep-23   14:08
Completed	Security Checked	15-Sep-23   14:08
Payment Events	Status	Timestamps