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3542 DN Utrecht, The Netherlands
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www.Diversey.com
Diversey - Lets Live

## **CERTIFICATE OF ANALYSIS**

Date issue: 06 November 2023

Product Name	CLEARKLENS IPA VH1				
Product Code	□ 101105062	<b>✓</b> 101105063	□ 101	105064	
Batch Number	FMP23285		58574		
<b>Production Date</b>	12/10/2023				
<b>Expiration Date</b>	EXP 12/10/2025				

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	Spec	cification	UOM	Results
Appearance	Appearance Visual Clear Colourless 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	58574
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK234055- 30664
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK234055- 30665



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

10/30/2023 10:39:11 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3440010 P.O.# 340620 Sales Order # 3420528

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/28/2023 18:46:39 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	538 BX	101105062	Diversey Clearklens IPA 900ml	FMP23294	58575/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	459 BX	101105063	Clearklens IPA 900 mls	FMP23285	58574/STR002201
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3 BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23285	58574/STR002201
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	1000 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 Reason Code Test	45.0 kGy	27.6 KGY	Pass	JATKINSON JOE ATKINSON	10/29/2023 17:43:44 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.2 KGY	Pass	JATKINSON JOE ATKINSON	10/29/2023 17:44:09 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: 10/30/2023 10:38:17 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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

R55480102 10/2

10/23/2023 9:48:40 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3432920 P.O.# 346540 Sales Order # 3412270

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 10/21/2023 18:16:17 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 975 ВХ 101105063 Clearklens IPA 900 mls FMP23285 58574/STR002201 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 975 BX Total

#### **Quality Test Summary**

						Signea 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	26.8 KGY	Pass	PSAXTON	10/22/2023 04:33:26 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.6 KGY	Pass	PSAXTON	10/22/2023 04:33:44 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: STEVEN WHELAN Date: 10/23/2023 09:47:59 GMT

Reason: Work Order Completions

## PHARMACEUTICAL ANALYSIS REPORT



#### Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs. Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23285 58574

Lucideon Sample Number: UK234055-30664

Lucideon Report Number: UK234055-30664/MFEP Issue Number: 1

Date Logged: 07-Nov-2023 Order Number: 406739

Date Reported: 28-Nov-2023 Date(s) of Test(s): 09-Nov-2023 to 23-Nov-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

D

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 28 November 2023 | 15:10 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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## **DocuSign**

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AutoNav: Enabled Queens Road

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Natalie.Boot@uk.lucideon.com IP Address: 86.188.222.148

Status: Completed

**Record Tracking** 

Status: Original Holder: Natalie Boot Location: DocuSign

28-Nov-23 | 15:09 Natalie.Boot@uk.lucideon.com

Signature **Signer Events Timestamp** Natalie Boot Sent: 28-Nov-23 | 15:10 Natalie Boot natalie.boot@uk.lucideon.com Viewed: 28-Nov-23 | 15:10 PlaceHolder Signed: 28-Nov-23 | 15:10 Lucideon Limited Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required), Authentication, Logged in 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.222.148

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Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	28-Nov-23   15:10
Certified Delivered	Security Checked	28-Nov-23   15:10
Signing Complete	Security Checked	28-Nov-23   15:10
Completed	Security Checked	28-Nov-23   15:10
Payment Events	Status	Timestamps

## PHARMACEUTICAL ANALYSIS REPORT



#### Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs. Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23285 58574

Lucideon Sample Number: UK234055-30665

Lucideon Report Number: UK234055-30665/ETEP Issue Number: 1

Date Logged: 07-Nov-2023 Order Number: 406739

Date Reported: 17-Nov-2023 Date(s) of Test(s): 16-Nov-2023 to 16-Nov-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

**End of Test Report** 

-DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 17 November 2023 | 12:34 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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## **DocuSign**

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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

17-Nov-23 | 12:33 Natalie.Boot@uk.lucideon.com

Signer Events	Signature	Timestamp
Natalie Boot natalie.boot@uk.lucideon.com PlaceHolder	Natalie Boot	Sent: 17-Nov-23   12:34 Viewed: 17-Nov-23   12:34 Signed: 17-Nov-23   12:34
Lucideon Limited Security Level: Email, Account Authentication (Required), Authentication	Signature Adoption: Pre-selected Style Signature ID: 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.222.148	
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Payment Events	Status	Timestamps
Completed	Security Checked	17-Nov-23   12:34
Signing Complete	Security Checked	17-Nov-23   12:34
Certified Delivered	Security Checked	17-Nov-23   12:34
Envelope Sent	Hashed/Encrypted	17-Nov-23   12:34
Envelope Summary Events	Status	Timestamps
Notary Events	Signature	Timestamp
Witness Events	Signature	Timestamp
Carbon Copy Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Editor Delivery Events	Status	Timestamp
In Person Signer Events	Signature	Timestamp