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Page 1 of 1

## **CERTIFICATE OF ANALYSIS**

Date issue: 30 November 2023

Product Name	CLEARKLENS IPA VH1				
Product Code	<b>✓</b> 101105062	□ 101105063		101105064	
<b>Batch Number</b>	FMP23311		58915		
<b>Production Date</b>	07/11/2023				
<b>Expiration Date</b>	EXP 07/11/2025				

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 Meth	od S	pecification	UOM	Results
Appearance	e Visual	Clear Co	olourless 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	58915
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK234412-33453
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK234412-33454



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

11/20/2023 13:49:40 GMT

Page 1 of 1

Cianad Die

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3448541 P.O.# Sales Order # 3430600

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 11/17/2023 12:59:00 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 650 вх 101105062 Diversey Clearklens IPA 900ml FMP23311 58915/STR002199 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 вх 650 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	39.3 KGY	Pass	LDAWSON	11/18/2023 00:59:18 GMT
		Reason Code Test				LINDSAY DAWSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	LDAWSON	11/18/2023 00:59:47 GMT
		Reason Code Test				LINDSAY DAWSON	

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: RHIANNON GATES Date: 11/20/2023 13:46:44 GMT

Reason: Work Order Completions



# **Certificate of Processing**

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R55480102

11/20/2023 13:50:28 GMT

Page 1 of 1

Cianad Die

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3449998 P.O.# Sales Order # 3432353

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 11/17/2023 15:55:33 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 1075 ВХ 101105062 Diversey Clearklens IPA 900ml FMP23311 58915/STR002199 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 вх 1075 Total

**Quality Test Summary** 

						Signea By	• •
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	LDAWSON	11/18/2023 06:33:55 GMT
		Reason Code Test				LINDSAY DAWSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.2 KGY	Pass	LDAWSON	11/18/2023 06:34:26 GMT
		Reason Code Test				LINDSAY DAWSON	

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: RHIANNON GATES Date: 11/20/2023 13:48:20 GMT

Reason: Work Order Completions



# **Certificate of Processing**

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

R55480102

11/27/2023 10:24:10 GMT

Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3456219 P.O.# 346881 Sales Order # 3439349

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 11/25/2023 11:42:18 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	427 BX	101105062	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	395 BX	100862174	Diversey Clearklens DE 900 mL	FMP23318	58916/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	825 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	45.0 kGy	39.8 KGY	Pass	CCICALA	11/27/2023 09:20:42 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.4 KGY	Pass	DYATES	11/26/2023 01:39:23 GMT
		Reason Code Test				DANIEL YATES	

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: 11/27/2023 10:23:31 GMT

Reason: Work Order Completions

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

Mrs. Olga Kirchner FAO:

ClearKlens IPA Report of Tests on:

**Sample Description:** Sample Code: Fmp23311 58915

Lucideon Sample Number: UK234412-33453

Lucideon Report Number: UK234412-33453/MFEP **Issue Number:** 

**Order Number: Date Logged:** 406976 01-Dec-2023

Date(s) of Test(s): 05-Dec-2023 to 19-Dec-2023 21-Dec-2023 **Date Reported:** 

> **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** 

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 21 December 2023 | 15:51 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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Source Envelope:

Document Pages: 2

Certificate Pages: 1

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Status: Completed

Envelope Originator:

Natalie Boot

Queens Road

Stoke-on-Trent, Staffordshire ST4 7LQ

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

**Record Tracking** 

Status: Original

21-Dec-23 | 15:48

Holder: Natalie Boot

Natalie.Boot@uk.lucideon.com

Location: DocuSign

Sent: 21-Dec-23 | 15:50

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**Timestamp** 

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**Signer Events** 

Natalie Boot

natalie.boot@uk.lucideon.com

PlaceHolder

Lucideon Limited

Security Level: Email, Account Authentication

(Required), Authentication, Logged in

Signature

Signatures: 2

Initials: 0

Notalie Boot

Signature Adoption: Pre-selected Style Signature ID:

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**Envelope Summary Events Status Timestamps** 

21-Dec-23 | 15:50 **Envelope Sent** Hashed/Encrypted Certified Delivered Security Checked 21-Dec-23 | 15:50

Signing Complete Security Checked 21-Dec-23 | 15:51 Completed Security Checked 21-Dec-23 | 15:51

**Payment Events Timestamps Status** 

## 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: Fmp23311 58915

Lucideon Sample Number: UK234412-33454

Lucideon Report Number: UK234412-33454/ETEP Issue Number: 1

Date Logged: 01-Dec-2023 Order Number: 406976

Date Reported: 14-Dec-2023 Date(s) of Test(s): 07-Dec-2023 to 07-Dec-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: 14 December 2023 | 09:53 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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## **Certificate Of Completion**

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**Envelopeld Stamping: Disabled** 

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Status: Completed

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Stoke-on-Trent, Staffordshire ST4 7LQ

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

## **Record Tracking**

Status: Original Holder: Natalie Boot

14-Dec-23 | 09:52 Natalie.Boot@uk.lucideon.com Location: DocuSign

#### Signature **Signer Events Timestamp** Natalie Boot Sent: 14-Dec-23 | 09:53 Natalie Boot natalie.boot@uk.lucideon.com Viewed: 14-Dec-23 | 09:53 PlaceHolder Signed: 14-Dec-23 | 09:53 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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Signing Complete	Security Checked	14-Dec-23   09:53
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Envelope Sent	Hashed/Encrypted	14-Dec-23   09:53
Envelope Summary Events	Status	Timestamps
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Intermediary Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Editor Delivery Events	Status	Timestamp
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