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www.Diversey.com
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## **CERTIFICATE OF ANALYSIS**

Date issue: 19 October 2023

<b>Product Name</b>	CLEARKLENS IPA VH1				
<b>Product Code</b>	<b>✓</b> 101105062	□ 101105063	□ 1	01105064	
<b>Batch Number</b>	FMP23273		58396		
<b>Production Date</b>	30/09/2023				
<b>Expiration Date</b>	EXP 30/09/2025				

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	Speci	fication	UOM	Results
Appearance	Visual	Clear Colour	less Liquid	NA	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872	0.883	g/cm3	0.876

## Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	58396
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK233851-29105
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK233851-29106



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

10/09/2023 11:04:37 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3425857 P.O.# 406420 Sales Order # 3404490

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	570 BX	101101081	Diversey Clearklens DE 900ml	FMP23270	58411/STR002096
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP23270	58411/STR002096
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	427 BX	101105062	Diversey Clearklens IPA 900ml	FMP23273	58396/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	1000 BX	Total			

#### **Quality Test Summary**

			quality 10	ot Guillian,	,	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	39.1 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	10/07/2023 15:31:10 GMT
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.7 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	10/07/2023 15:31:36 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: 10/09/2023 11:04:16 GMT

Reason: Work Order Completions



# **Certificate of Processing**

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

R55480102

10/16/2023 9:02:46 GMT

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Cianad Die

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3428904 P.O.# 3407810

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 10/15/2023 06:37:36 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 FMP23273 58396/STR002199 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 вх 1075 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	JATKINSON	10/16/2023 03:41:14 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	JATKINSON	10/16/2023 03:41:45 GMT
		Reason Code Test				JOE ATKINSON	

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: 10/16/2023 08:57:20 GMT

Reason: Work Order Completions



# **Certificate of Processing**

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R55480102

10/16/2023 9:02:38 GMT

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**Customer Name:** FLEXIBLE MED. GBP UK LANCASTER **Processing Facility:** Markham Vale Work Order # 3429871 P.O.# 406474 Sales Order # 3408820

25 - 45 kGy **Gamma Irradiation** Irradiation Date/Time: 10/15/2023 03:17:47 GMT

SO Line #	Qty UOI	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	646 BX	101105062	Diversey Clearklens IPA 900ml	FMP23273	58396/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23273	58396/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	160 BX	101101081	Diversey Clearklens DE 900ml	FMP23270	58411/STR002096
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	16 BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP23270	58411/STR002096
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	825 BX	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	38.3 KGY	Pass	LDAWSON	10/15/2023 15:19:48 GMT
		Reason Code Tes	st			LINDSAY DAWSON	
450.00	) Minimum Dose	25.0 kGy	45.0 kGy	27.0 KGY	Pass	LDAWSON	10/15/2023 15:20:21 GMT
		Reason Code Tes	st .			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: CLAIRE CICALA
Reason: Work Order Completions Date: 10/16/2023 08:57:48 GMT

## 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: Fmp23273 58396

Lucideon Sample Number: UK233851-29105

Lucideon Report Number: UK233851-29105/MFEP Issue Number: 1

Date Logged: 20-Oct-2023 Order Number: 406597

Date Reported: 13-Nov-2023 Date(s) of Test(s): 26-Oct-2023 to 09-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



Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 13 November 2023 | 13:54 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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# **DocuSign**

### **Certificate Of Completion**

Envelope Id: B135F3F0B8C649B689D6D28E055C9FBE

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

Subject: Sign Source Envelope:

Document Pages: 1 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Natalie Boot

AutoNav: Enabled Queens Road

Envelopeld Stamping: Disabled Stoke-on-Trent, Staffordshire ST4 7LQ

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

Status: Completed

**Record Tracking** 

Status: Original Holder: Natalie Boot Location: DocuSign

13-Nov-23 | 13:53 Natalie.Boot@uk.lucideon.com

Signature **Signer Events Timestamp** Natalie Boot Sent: 13-Nov-23 | 13:54 Natalie Boot natalie.boot@uk.lucideon.com Viewed: 13-Nov-23 | 13:54 PlaceHolder Signed: 13-Nov-23 | 13:54 Lucideon Limited Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required), Authentication 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.245.148

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With Signing Reasons (on each tab):
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#### **Electronic Record and Signature Disclosure:**

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Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	13-Nov-23   13:54
Certified Delivered	Security Checked	13-Nov-23   13:54
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	Security Checked	10 1407 20   10.04
Completed	Security Checked	13-Nov-23   13:54

## 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: Fmp23273 58396

Lucideon Sample Number: UK233851-29106

Lucideon Report Number: UK233851-29106/ETEP Issue Number: 1

Date Logged: 20-Oct-2023 Order Number: 406597

Date Reported: 25-Oct-2023 Date(s) of Test(s): 24-Oct-2023 to 24-Oct-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

U

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 25 October 2023 | 11:33 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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# **DocuSign**

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Envelope Id: CDD8E2700BFF4C60936C31125412845F

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Document Pages: 1 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Natalie Boot
AutoNav: Enabled Queens Road

Envelopeld Stamping: Disabled Stoke-on-Trent, Staffordshire ST4 7LQ

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

Natalie.Boot@uk.lucideon.com

IP Address: 86.188.245.148

Status: Completed

### **Record Tracking**

Status: Original Holder: Natalie Boot Location: DocuSign

25-Oct-23 | 11:32 Natalie.Boot@uk.lucideon.com

Signer Events	Signature	Timestamp
Natalie Boot		Sent: 25-Oct-23   11:33
natalie.boot@uk.lucideon.com	Natalie Boot	Viewed: 25-Oct-23   11:33
PlaceHolder		Signed: 25-Oct-23   11:33
Lucideon Limited	Cignoture Adention: Dre colected Stule	
Security Level: Email, Account Authentication (Required), Authentication, Logged in	Signature Adoption: Pre-selected Style Signature ID: 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.245.148	
	With Signing Authentication via DocuSign passwo With Signing Reasons (on each tab):	rd

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

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Envelope Summary Events  Envelope Sent Certified Delivered Signing Complete Completed	Status Hashed/Encrypted Security Checked Security Checked Security Checked	Timestamps 25-Oct-23   11:33 25-Oct-23   11:33 25-Oct-23   11:33 25-Oct-23   11:33
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Envelope Summary Events Envelope Sent	Hashed/Encrypted	25-Oct-23   11:33
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