

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: 18 January 2024

Product Name	CLEARKLENS IPA VH1			
<b>Product Code</b>	<b>✓</b> 101105062	□ 101105063		101105064
<b>Batch Number</b>	FMP24002		59249	
<b>Production Date</b>	02/01/2024			
<b>Expiration Date</b>	EXP 02/01/2026			

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 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	59249
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK24227-1418
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK24227-1419



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

01/15/2024 13:44:38 GMT

Page 1 of 1

-----Signed By

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3478887 P.O.# 3406953

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 01/13/2024 00:32:26 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 FMP24002 59249/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	27.2 KGY	Pass	JYATES	01/13/2024 14:51:26 GMT
		Reason Code Test				JOHN YATES	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.7 KGY	Pass	JYATES	01/13/2024 14:51:42 GMT
		Reason Code Test				JOHN 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: RHIANNON GATES Date: 01/15/2024 13:34:14 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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

R55480102

01/15/2024 13:44:26 GMT

Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3481368 P.O.# 3407248 Sales Order # 3469704

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 01/12/2024 19:46:56 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1070	вх	101105062	Diversey Clearklens IPA 900ml	FMP24002	59249/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	5	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP24002	59249/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	1075	вх	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	27.2 KGY	Pass	JYATES	01/13/2024 14:49:24 GMT
		Reason Code Test				JOHN YATES	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.6 KGY	Pass	JYATES	01/13/2024 14:49:40 GMT
		Reason Code Test	t			JOHN 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: RHIANNON GATES Date: 01/15/2024 13:33:39 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: Fmp24002 59249

Lucideon Sample Number: UK24227-1419

Issue Number: Lucideon Report Number: UK24227-1419/ETEP

Order Number: 407298 **Date Logged:** 19-Jan-2024

Date(s) of Test(s): 14-Feb-2024 to 14-Feb-2024 **Date Reported:** 15-Feb-2024

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:

Notalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 15 February 2024 | 14:35 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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query@lucideon.com www.lucideon.com Staffordshire, ST4 7LQ, UK Reg. England 1960455

## **DocuSign**

#### **Certificate Of Completion**

Envelope Id: ECED2BA23E8E47D48E4A2523785BE047

Subject: Complete with DocuSign: DataWindow.xps

Source Envelope:

Document Pages: 3

Certificate Pages: 1

AutoNav: Enabled

Envelopeld Stamping: Disabled

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

Status: Completed

Envelope Originator:

Natalie Boot

Queens Road

Stoke-on-Trent, Staffordshire \$T4.7LQ

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

#### **Record Tracking**

Status: Original

15-Feb-24 | 14:32

Holder: Natalie Boot

Natalie.Boot@uk.lucideon.com

Location: DocuSign

Sent: 15-Feb-24 | 14:35

Viewed: 15-Feb-24 | 14:35 Signed: 15-Feb-24 | 14:35

**Timestamp** 

## **Signer Events**

Natalie Boot

natalie.boot@uk.lucideon.com

PlaceHolder

Lucideon Limited

Security Level: Email, Account Authentication (Required), Authentication

#### **Signature**

Signatures: 3

Initials: 0

Natalic Boot

Signature Adoption: Pre-selected Style

Signature ID:

90369E90-4813-4123-B65D-5E8FBD375BF3

Using IP Address: 86.188.245.148

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

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**Electronic Record and Signature Disclosure:** 

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Signature	Timestamp	
Status	Timestamp	
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Signature	Timestamp	
Status	Timestamps	
Hashed/Encrypted	15-Feb-24   14:35	
Security Checked	15-Feb-24   14:35	
Security Checked	15-Feb-24   14:35	
Security Checked	15-Feb-24   14:35	
Status	Timestamps	
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## 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: Fmp24002 59249

Lucideon Sample Number: UK24227-1418

Lucideon Report Number: UK24227-1418/MFEP

Issue Number:

**Date Logged:** 

19-Jan-2024

Order Number:

407298

**Date Reported:** 

15-Feb-2024

Date(s) of Test(s):

01-Feb-2024 to 15-Feb-2024

**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: 15 February 2024 | 14:35 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

Page 1 of 1

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Subject: Complete with DocuSign: DataWindow.xps

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Document Pages: 3

Certificate Pages: 1 AutoNav: Enabled

Envelopeld Stamping: Disabled

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Envelope Originator:

Natalie Boot

Queens Road

Stoke-on-Trent, Staffordshire ST4 7LQ

Natalie.Boot@uk.lucideon.com

IP Address: 86.188.245.148

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15-Feb-24 | 14:32

Holder: Natalie Boot

Natalie.Boot@uk.lucideon.com

Location: DocuSign

Sent: 15-Feb-24 | 14:35

Viewed: 15-Feb-24 | 14:35 Signed: 15-Feb-24 | 14:35

**Timestamp** 

## **Signer Events**

Natalie Boot

natalie.boot@uk.lucideon.com

PlaceHolder

Lucideon Limited

Security Level: Email, Account Authentication

(Required), Authentication

#### Signature

Signatures: 3

Initials: 0

Natalie Boot

Signature Adoption: Pre-selected Style

Signature ID:

90369E90-4813-4123-B65D-5E8FBD375BF3

Using IP Address: 86.188.245.148

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

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

Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp	
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Certified Delivery Events	Status	Timestamp	
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Witness Events	Signature	Timestamp	
Notary Events	Signature	Timestamp	
Envelope Summary Events	Status	Timestamps	
Envelope Sent	Hashed/Encrypted	15-Feb-24   14:35	
Certified Delivered	Security Checked	15-Feb-24   14:35	
Signing Complete	Security Checked	15-Feb-24   14:35	
Completed	Security Checked	15-Feb-24   14:35	
Payment Events	Status	Timestamps	