

Diversey Europe Operations BV Masrasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date: 11/10/2019

CLEARKLENS IPA VH1				
7514372				
FMP 19241 48026				
291 08 1 2019				
EXP 29 108 12021				

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	Lin Lower	Results Clear Colour less Liquid	
Appearance	Visual	Clear Colourless Liquid		
Specific Gravity (20°C)	DM004	0.872	0.883	0.817

On behalf of Diversey site	Name:	Party Stor 7 Storm
Quality Manager	Position	Quality Contro Inspector

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COA Template Version : 02 Date of Issuing : November 24 2017

### PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp 19241 48026

Lucideon Sample Number: (195667)-43300

Lucideon Report Number: (195667)-43300/MFEP

Issue Number:

Date Logged:

11-Oct-2019

**Order Number:** 

34061

**Date Reported:** 

01-Nov-2019

Date(s) of Test(s):

15-Oct-2019 to 29-Oct-2019

**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** 

1 10300+ 01-NOV-19

Mrs Natalie Boot

Senior Business Support Assistant

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

## PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp 19241 48026

Lucideon Sample Number: (195667)-43301

Lucideon Report Number: (195667)-43301/ETEP

Issue Number:

1

Date Logged:

11-Oct-2019

Order Number:

34061

**Date Reported:** 

Date(s) of Test(s):

22-Oct-2019

18-Oct-2019 to 22-Oct-2019

**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 (<0.2 EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 

NOBOOT 22-OCT-A.

Mrs Natalie Boot

Senior Business Support Assistant

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# **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102 10/0

10/03/2019 12:27:41 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2525084 P.O.# P033969 Sales Order # 2334056

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/02/2019 10:17:04 GMT

SO Line #	Qty l	JOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	879 E	ЗХ	7513400	Diversey Clearklens IPA 900 mL	FMP19232	WO47809 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	536 E	ЗХ	7514372	Diversey Clearklens IPA 900 mL	FMP19241	WO48026 / DEV001250
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5 E	ЗХ	7514372 Sample	Diversey Clearklens IPA 900 mL	FMP19241	WO48026/ DEV001250
	Dose Map <b>1420</b> E	вх	302_0030 <b>Total</b>	Ref Pos: 10E1, AF Min = 0.71		

#### **Quality Test Summary**

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	26.6 KGY	Pass	TKVARDA TOMAS KVARDA	10/03/2019 10:58:23 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.2 KGY	Pass	TKVARDA TOMAS KVARDA	10/03/2019 10:58:49 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: EMMA SILLS Date: 10/03/2019 12:26:54 GMT

Reason: Work Order Completions



# **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102 10

10/07/2019 15:02:49 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2527301 P.O.# PO33995 Sales Order # 2336796

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/05/2019 11:02:42 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	175 BX	7514372	Diversey Clearklens IPA 900 mL	FMP19241	WO48026 / DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	700 BX	7513400	Diversey Clearklens IPA 900 mL	FMP19254	WO48034 / DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19254	WO48034/ DEV001152
	Dose Map <b>880 BX</b>	302_0030 <b>Total</b>	Ref Pos: 10E1, AF Min = 0.71		

#### **Quality Test Summary**

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.0 KGY	Pass	PSAXTON DALL SAXTON	10/07/2019 09:00:04 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.3 KGY	Pass	PSAXTON	10/07/2019 09:00:26 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: ASHLEY HOBSON Date: 10/07/2019 15:01:00 GMT

Reason: Work Order Completions