

Diversey Europe Operations BV Magrasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date:

23 June 2021

Product Name	CL	EARKLENS IPA VH1	
Product Code	7513400		
Batch Number	FMP21137	51840	
Production Date	17/05/2021	333.13	
Expiration Date	EXP 17/05/2023		

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	Limi Lower	ts - Upper	Results	
Appearance	Visual	Visual Clear Colourless Liquid		Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.872	0.883	0.875	

On behalf of Diversey site	Name:	Angelika Partynska Justyna Staron
Quality Manger	Position	Quality Control Inspector

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COA Template Version: 02 Date of issuing: November 24th



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

R55480102

06/01/2021 10:13:23 GMT Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2892386 P.O.# PO38099 Sales Order # 2777937

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 05/29/2021 10:58:34 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	877 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21120	WO51689/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	4 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP21120	WO51689/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
103.000	69 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21137	WO51840/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
	950 BX	Total			

### **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	27.6 KGY	Pass	IWEATHERAL IAN WEATHERALL	05/29/2021 21:41:45 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.7 KGY	Pass	IWEATHERAL IAN WEATHERALL	05/29/2021 21:42:08 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: ASHLEY HOBSON Date: 06/01/2021 10:12:41 GMT



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

R55480102 05

05/24/2021 13:44:16 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2892534 P.O.# PO38045 Sales Order # 2778012

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 05/22/2021 05:16:12 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	392 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21117	WO51688/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	3 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP21117	WO51688/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
103.000	545 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21120	WO51689/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
104.000	10 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21137	WO51840/DEV001152
	Dose Map <b>950 BX</b>	302_0112 <b>Total</b>	REF: 13.5A3 AF Min = 0.717		

### **Quality Test Summary**

	Ор#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
-	450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.4 KGY	Pass	JYATES	05/22/2021 17:07:43 GMT
			Reason Code Test				JOHN YATES	
	450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	JYATES	05/22/2021 17:07:59 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: EMMA SILLS Date: 05/24/2021 13:43:52 GMT



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R55480102

06/14/2021 11:07:52 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2894988 P.O.# PO38142 Sales Order # 2781143

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 06/11/2021 01:04:33 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 950 ВХ 7513400 Diversey Clearklens IPA 900 mL FMP21137 WO51840/DEV001152 Dose Map REF: 13.5A3 AF Min = 0.717 302 0112 вх 950 Total

**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 kGv	27.7 KGY	Pass	JYATES	06/11/2021 17:14:54 GMT
130.00	William Bose	Reason Code Test		27.7 1101	1 433	JOHN YATES	00/11/2021 17:14.54 01111
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	JYATES	06/11/2021 17:15:09 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: EMMA SILLS Date: 06/14/2021 11:07:42 GMT



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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2895110 P.O.# PO38154 Sales Order # 2781297

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 06/11/2021 05:24:49 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	398 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21137	WO51840/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	3 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP21137	WO51840/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
103.000	549 BX	7513400	Diversey Clearklens IPA 900 mL	FMP21140	WO51841/DEV001152
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
	950 BX	Total			

### **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	27.7 KGY	Pass	JYATES JOHN YATES	06/11/2021 17:18:37 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.1 KGY	Pass	JYATES JOHN YATES	06/11/2021 17:18:52 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: 06/14/2021 11:01:54 GMT

## PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp21137 51840

Lucideon Sample Number: UK212768-18918

Lucideon Report Number: UK212768-18918/ETEP

Issue Number:

Date Logged:

25-Jun-2021

Order Number:

400144

**Date Reported:** 

08-Jul-2021

Date(s) of Test(s):

06-Jul-2021

to 06-Jul-2021

**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 (<0.2000EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 

15-1UE-80 10080U

Mrs Natalie Boot

**Business Support Administrator** 

## 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: Fmp21137 51840

Lucideon Sample Number: UK212768-18917

Lucideon Report Number: UK212768-18917/MFEP

**Issue Number:** 

Date Logged:

25-Jun-2021

Order Number:

400144

**Date Reported:** 

14-Jul-2021

Date(s) of Test(s):

30-Jun-2021 to 14-Jul-2021

**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** 

