

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

25 August 2020

Product Name	CLEARKLENS IPA VH1				
Product Code	7513400				
Batch Number	FMP20195	49732			
Production Date	13/07/2020				
Expiration Date	EXP 13/07/2022				

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	Clear Colou	rless Liquid	Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.872	0.883	0.877	

O., h.l16 - CDi	Name:	Justyna Staron	Angelika Partynska
On behalf of Diversey site  Quality Manger	Position	Quality	y Control Inspector

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



## **Certificate of Processing**

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

R55480102 07/3

07/31/2020 12:38:31 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2705034 P.O.# P035963 Sales Order # 2547943

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 07/30/2020 01:42:49 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	219 BX	7514372	Diversey Clearklens IPA 900 mL	FMP20191	WO49731/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3 BX	7514372 Sample	Diversey Clearklens IPA 900 mL	FMP20191	WO49731/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	718 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20195	WO49732/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	940 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	JATKINSON JOE ATKINSON	07/30/2020 14:34:18 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.9 KGY	Pass	JATKINSON JOE ATKINSON	07/30/2020 14:34:46 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: 07/31/2020 12:33:38 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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R55480102 07/3

07/31/2020 12:59:41 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2707655
P.O.# PO35986 Sales Order # 2550997

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 07/30/2020 08:41:04 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number **Load Number** WO49732/DEV001152 101.000 660 ВХ 7513400 Diversey Clearklens IPA 900 mL FMP20195 Dose Map Ref Pos: 10E1, AF Min = 0.71 302 0030 вх 660 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	27.9 KGY	Pass	JATKINSON	07/31/2020 10:15:23 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	41.4 KGY	Pass	JATKINSON	07/31/2020 10:15:53 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: ASHLEY HOBSON Date: 07/31/2020 12:57:19 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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

R55480102

08/17/2020 8:49:46 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2713669 P.O.# PO36043 Sales Order # 2558785

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 08/14/2020 23:57:54 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	48 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20195	WO49732 / DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20195	WO49732/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	908 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20209	WO49795/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	1 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20209	WO49795/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	960 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	41.1 KGY	Pass	ESILLS	08/17/2020 08:10:31 GMT
		Reason Code Test				EMMA SILLS	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.9 KGY	Pass	IWEATHERAL	08/15/2020 17:18:24 GMT
		Reason Code Test				IAN WEATHERALL	

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: 08/17/2020 08:47:32 GMT

Reason: Work Order Completions

## 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: Fmp20195 49732

Lucideon Sample Number: UK203475-24441

Lucideon Report Number: UK203475-24441/MFEP

Issue Number:

Date Logged:

26-Aug-2020

Order Number:

PO 36272

**Date Reported:** 

17-Sep-2020

Date(s) of Test(s):

29-Aug-2020 to 12-Sep-2020

**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** 

NOBOOT 17-SED-80

Mrs Natalie Boot

Senior Business Support Assistant

### 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: Fmp20195 49732

Lucideon Sample Number: UK203475-24442

Lucideon Report Number: UK203475-24442/ETEP

Issue Number:

Date Logged:

26-Aug-2020

Order Number:

PO 36272

Date Reported:

25-Sep-2020

Date(s) of Test(s):

10-Sep-2020 to 10-Sep-2020

**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 (<0.2EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 

Mrs Andrea Saunders

**Business Support Assistant** 

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