

Diversey Europe Operations BV Maarasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

26 August 2020

Product Name	CLEARKLENS IPA VH1				
Product Code	7513400				
Batch Number	FMP20223	50029			
Production Date	10/08/2020				
Expiration Date	EXP 10/08/2022				

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  Clear Colourless Liquid	
Appearance	Visual	Clear Colou	ırless Liquid		
Specific Gravity (20°C)	DM004	0.872	0.883	0.873	

On behalf of Diversey site	Name:	Justyna Staron Angelika Partynsk		
Quality Manger	Position	Quality	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

08/24/2020 8:32:41 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2720938 P.O.# PO36176 Sales Order # 2567917

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 08/23/2020 01:20:14 GMT

SO Line #	Qty UO	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	889 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20223	WO50029/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	11 BX	100862174	Diversey Clearklens DE 900 mL	FMP20218	WO50028/DEV001910
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	900 BX	Total			

#### **Quality Test Summary**

						Signed By	
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.0 KGY	Pass	BCZAPLA	08/23/2020 14:54:04 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	BCZAPLA	08/23/2020 14:55:29 GMT
		Reason Code Test				BARTOSZ CZAPLA	

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: 08/24/2020 08:30:27 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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

R55480102

08/24/2020 9:44:37 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2722685 P.O.# PO36194 Sales Order # 2569982

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 08/22/2020 18:29:47 GMT

SO Line #	Qty U	ЮМ	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	530 B	X	7513400	Diversey Clearklens IPA 900 mL	FMP20223	WO50029/DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	10 B	X	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20223	WO50029/DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	540 B	X	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 Reason Code Test	45.0 kGy	40.5 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	08/23/2020 14:34:10 GMT
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.4 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	08/23/2020 14:34:24 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: 08/24/2020 09:42:19 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:

Clear Klens IPA

Sample Description:

Sample Code: Fmp20223 50029

Lucideon Sample Number: UK203514-24638

Lucideon Report Number: UK203514-24638/MFEP

Issue Number:

Date Logged:

27-Aug-2020

Order Number:

PO 36279

**Date Reported:** 

21-Sep-2020

Date(s) of Test(s):

04-Sep-2020 to 18-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** 



**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: Fmp20223 50029

Lucideon Sample Number: UK203514-24639

Lucideon Report Number: UK203514-24639/ETEP

Issue Number:

Date Logged:

27-Aug-2020

Order Number:

PO 36279

**Date Reported:** 

06-Oct-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:

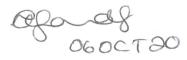
The test results meet the EP/USP criteria: Yes

Result: Pass (<0.2EU/ml)

Tests carried out in accordance with cGMP

Refer to laboratory investigation report (LIR) 0609.

**End of Test Report** 



Mrs Andrea Saunders

**Business Support Assistant**