

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

23 February 2021

Product Name	CLEARKLENS DE VH29					
Product Code	101101081					
Batch Number	FMP20357	51119				
Production Date	22/12/2020	VIII)				
Expiration Date	EXP 22/12/2022					

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	its - Upper	Results	
Appearance	Visual	Clear Color	rless Liquid	Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.880	0.888	0.885	

On behalf of Diversey site	Name:	Urszula Haraburda Angelika Partynska
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

01/18/2021 11:26:43 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2805813 P.O.# PO37134 Sales Order # 2671966

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 01/16/2021 00:09:55 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	640 BX	7514372	Diversey Clearklens IPA 900 mL	FMP20356	WO51118/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3 BX	7514372 Sample	Diversey Clearklens IPA 900 mL	FMP20356	WO51118/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	217 BX	101101081	Diversey Clearklens DE 900ml	FMP20357	WO51119/DEV002096
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	860 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	27.8 KGY	Pass	DMARRIOTT DAVID MARRIOTT	01/16/2021 15:55:08 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	40.1 KGY	Pass	DMARRIOTT DAVID MARRIOTT	01/16/2021 15:55:28 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: 01/18/2021 11:23:29 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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R55480102 01/18/2021 11:14:18 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2806536 P.O.# PO37152 Sales Order # 2672869

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 01/15/2021 17:04:14 GMT

SO Line #	Qty U	JOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	482 B	ЗХ	101101081	Diversey Clearklens DE 900ml	FMP20357	WO51119/DEV002096
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3 B	ЗХ	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP20357	WO51119/DEV002096
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	375 B	ЗХ	101100418	Diversey Clearklens IPA/DE 900	FMP21004	WO51120/DEV002080
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	860 B	3X	Total			

#### **Quality Test Summary**

			quanty 10	or ourman	,	Signed By	
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	27.5 KGY	Pass	SWARD SIMON WARD	01/16/2021 05:08:03 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.5 KGY	Pass	SWARD SIMON WARD	01/16/2021 05:08:35 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: 01/18/2021 11:08:13 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 DE

Sample Description:

Sample Code: Fmp20357 51119

Lucideon Sample Number: UK21757-5203

Lucideon Report Number: UK21757-5203/ETEP

Issue Number:

Date Logged:

22-Feb-2021

Order Number:

PO 37501

**Date Reported:** 

26-Feb-2021

Date(s) of Test(s):

24-Feb-2021 to 24-Feb-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 (<0.2EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 



Mrs Natalie Boot

**Business Support Administrator** 

### 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 DE

Sample Description:

Sample Code: Fmp20357 51119

Lucideon Sample Number: UK21757-5202

Lucideon Report Number: UK21757-5202/MFEP

Issue Number:

1

Date Logged:

22-Feb-2021

Order Number:

PO 37501

**Date Reported:** 

12-Mar-2021

Date(s) of Test(s):

26-Feb-2021 to 12-Mar-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** 

NOBOOK 12-MOr-21

Mrs Natalie Boot

**Business Support Administrator**