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CERTIFICATE OF ANALYSIS

Date: 25 August 2020

Product Name	CLEARKLENS DE VH29		
Product Code	100862174		
Batch Number	FMP20218	50028	
Production Date	05/08/2020		
Expiration Date	EXP 05/08/2022		

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	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.880	0.888	0.881

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

This document being issued electronically does not bear a signature

COA Template

Version : 02

Date of issuing : November 24th

R55480102

 08/17/2020 9:29:05 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2717972
P.O.#	PO36116			Sales Order #	2564031
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	08/15/2020 06:19:07 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	380	BX	100862174	Diversey Clearklens DE 900 mL	FMP20218	WO50028/DEV001910
			Dose Map	302_0030		
	380	BX	Total	Ref Pos: 10E1, AF Min = 0.71		

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By-----	
						User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.0 KGY	Pass	ESILLS	08/17/2020 09:15:45 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.1 KGY	Pass	JATKINSON	08/17/2020 07:39:28 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: EMMA SILLS
 Reason: Work Order Completions

Date: 08/17/2020 09:26:46 GMT

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 08/17/2020 7:47:21 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2718853
P.O.#	PO36132			Sales Order #	2565131
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	08/15/2020 08:37:37 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	317	BX	100862174	Diversey Clearklens DE 900 mL	FMP20218	WO50028/DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3	BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP20218	WO50028/DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	320	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.1 KGY	Pass	ESILLS	08/17/2020 07:39:24 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	TKVARDA	08/16/2020 03:43:30 GMT
		Reason Code Test				TOMAS KVARDA	

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
 Reason: Work Order Completions

Date: 08/17/2020 07:45:06 GMT

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 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	UOM	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

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

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
 Reason: Work Order Completions

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

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: Fmp20218 50028

Lucideon Sample Number: UK203475-24439

Lucideon Report Number: UK203475-24439/MFEP **Issue Number:** 1

Date Logged: 26-Aug-2020 **Order Number:** PO 36272

Date Reported: 21-Sep-2020 **Date(s) of Test(s):** 03-Sep-2020 to 17-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



Mrs Andrea Saunders

Business Support Assistant

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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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: Fmp20218 50028

Lucideon Sample Number: UK203475-24440

Lucideon Report Number: UK203475-24440/ETEP **Issue Number:** 1

Date Logged: 26-Aug-2020 **Order Number:** PO 36272

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


06 OCT 20

Mrs Andrea Saunders

Business Support Assistant

Page 1 of 1

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