

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

16 April 2020

Product Name	CLEARKLENS DE VH29			
Product Code	100862174			
Batch Number	FMP20086	49158		
Production Date	26/03/2020			
Expiration Date	EXP 26/03/2022			

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 Colourless Liquid		Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.880	0.888	0.881	

On behalf of Diversey site	Name:	Angelika Partynska urszula Haraburda
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

04/14/2020 9:08:49 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2643046 P.O.# PO35164 Sales Order # 2473389

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 04/08/2020 16:02:49 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	12 BX	101101081	Diversey Clearklens DE 900ml	FMP20083	WO49600/DEV002096
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	8 BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP20083	WO49600/DEV002096
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	697 BX	100862174	Diversey Clearklens DE 900 mL	FMP20086	WO49158/DEV001910
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	3 BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP20086	WO49158/DEV001910
	Dose Map <b>720 BX</b>	302_0030 <b>Total</b>	Ref Pos: 10E1, AF Min = 0.71		

#### **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 kGy	27.5 KGY	Pass	DMATHIAS	04/09/2020 09:45:40 GMT
		Reason Code Test				DAVID MATHIAS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	41.8 KGY	Pass	DMATHIAS	04/09/2020 09:46:07 GMT
		Reason Code Test				DAVID MATHIAS	

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: 04/14/2020 09:07:06 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 DE

**Sample Description:** 

Sample Code: Fmp20086 49158

Lucideon Sample Number: UK201736-13203

Lucideon Report Number: UK201736-13203/MFEP

Issue Number:

Date Logged:

17-Apr-2020

**Order Number:** 

PO 35249

**Date Reported:** 

05-May-2020

Date(s) of Test(s):

20-Apr-2020 to 04-May-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** 

NOBOOK OS-MOY-20 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 DE

Sample Description:

Sample Code: Fmp20086 49158

Lucideon Sample Number: UK201736-13204

Lucideon Report Number: UK201736-13204/ETEP

Issue Number:

Date Logged:

17-Apr-2020

Order Number:

PO 35249

**Date Reported:** 

12-May-2020

Date(s) of Test(s):

09-May-2020 to 09-May-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 (<0.2 EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 

Mrs Andrea Saunders

**Business Support Assistant**