

Diversey Europe Operations 5V Maarasenbrooksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date:

12 February 2020

Product Name	CLEARKLENS IPA VH1			
Product Code	7514372			
Batch Number	FMP20028	49136		
Production Date	28/01/2020			
Expiration Date	EXP 28/01/2022			

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	0.872	0.883	0.877	

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
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## **Certificate of Processing**

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

R55480102

02/06/2020 10:59:13 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2604250 P.O.# PO34708 Sales Order # 2427011

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 02/05/2020 09:16:38 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	58 BX	100862174	Diversey Clearklens DE 900 mL	FMP19322	WO48698/DEV001910
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	530 BX	7514372	Diversey Clearklens IPA 900 mL	FMP20028	WO49136/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	3 BX	7514372 Sample	Diversey Clearklens IPA 900 mL	FMP20028	WO49136/DEV001250
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	9 BX	FMP Dunnage Boxes	Customer Supplied	T019/167	T019/167
	Dose Map <b>600 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	27.8 KGY	Pass	IWEATHERAL	02/05/2020 23:00:53 GMT
		Reason Code Test				IAN WEATHERALL	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.8 KGY	Pass	IWEATHERAL	02/05/2020 23:01:17 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: 02/06/2020 10:57:31 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:

ClearKlens IPA

Sample Description:

Sample Code: Fmp20028 49136

Lucideon Sample Number: UK20745-5569

Lucideon Report Number: UK20745-5569/ETEP

Issue Number:

Date Logged:

13-Feb-2020

Order Number:

PO 34767

**Date Reported:** 

24-Feb-2020

Date(s) of Test(s):

14-Feb-2020 to 14-Feb-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** 



This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp20028 49136

Lucideon Sample Number: UK20745-5568

Lucideon Report Number: UK20745-5568/MFEP

Issue Number:

Date Logged:

13-Feb-2020

**Order Number:** 

PO 34767

**Date Reported:** 

05-Mar-2020

Date(s) of Test(s):

16-Feb-2020 to 01-Mar-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** 

at as-Mar-20 Mrs Natalie Boot

Senior Business Support Assistant

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Lucideon Limited

Stoke-on-Trent