

Diversey Europe Operations BV Maarasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

04 November 2020

Product Name	CLEARKLENS IPA VH1				
Product Code	7513400				
Batch Number	FMP20287	50907			
Production Date	13/10/2020				
Expiration Date	EXP 13/10/2022		_		

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 Colou	rless Liquid	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872	0.883	0.873

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 10/2

10/26/2020 9:27:41 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2759334
P.O.# PO36632 Sales Order # 2614438

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/23/2020 16:36:34 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	162 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20281	WO50908/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	4 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20281	WO50908/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	234 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20287	WO50907/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	400 BX	Total			

#### **Quality Test Summary**

						Signed By	-
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.1 KGY	Pass	DMARRIOTT	10/24/2020 11:45:31 GMT
		Reason Code Test				DAVID MARRIOTT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.2 KGY	Pass	DMARRIOTT	10/24/2020 11:45:52 GMT
		Reason Code Test				DAVID MARRIOTT	

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: 10/26/2020 09:25:03 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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

R55480102

10/26/2020 10:36:14 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2760232 P.O.# PO36635 Sales Order # 2615600

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/23/2020 23:40:48 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number **Load Number** WO50907/DEV001152 101.000 960 ВХ 7513400 Diversey Clearklens IPA 900 mL FMP20287 Dose Map Ref Pos: 10E1, AF Min = 0.71 302 0030 вх 960 Total

**Quality Test Summary** 

						Signea By	• •
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	26.9 KGY	Pass	TKVARDA	10/24/2020 16:18:56 GMT
		Reason Code Test				TOMAS KVARDA	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.3 KGY	Pass	TKVARDA	10/24/2020 16:19:23 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 Date: 10/26/2020 10:33:34 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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11/02/2020 11:15:43 GMT Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2763147 P.O.# PO36657 Sales Order # 2618959

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 10/30/2020 02:41:41 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	191 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20294	WO50204/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	226 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20287	WO50907/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	3 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20287	WO50907/DEV001152
	Dose Map <b>420 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 Reason Code Test	45.0 kGy	26.7 KGY	Pass	DMARRIOTT DAVID MARRIOTT	10/31/2020 04:51:07 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	41.1 KGY	Pass	DMARRIOTT DAVID MARRIOTT	10/31/2020 04:51:25 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: 11/02/2020 11:13:03 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: Fmp20287 50907

Lucideon Sample Number: UK204522-32026

Lucideon Report Number: UK204522-32026/ETEP

Issue Number:

Date Logged:

05-Nov-2020

Order Number:

PO36754

**Date Reported:** 

Date(s) of Test(s):

12-Nov-2020 to 12-Nov-2020

02-Dec-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) 0640.

**End of Test Report** 



Mrs Andrea Saunders

**Business Support Assistant** 

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 LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp20287 50907

Lucideon Sample Number: UK204522-32025

Lucideon Report Number: UK204522-32025/MFEP

Issue Number:

Date Logged:

05-Nov-2020

Order Number:

PO36754

Date Reported:

02-Dec-2020

Date(s) of Test(s):

13-Nov-2020 to 27-Nov-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**