

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 27/11/2019

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	EMP10311 48609
Production Date	02/11/2019
Expiration Date	EXP 031 112021

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	Lin Lower -	its Upper	Results
Appearance	Visual	Clear Co	Clear Colourless	
Specific Gravity (20°C)	DM004	0.872	0.883	0.881

On behalf of Diversey site	Name:	Marabuda Partyesto
Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template Version: 02 Date of issuing: November 24<sup>th</sup> 2017



## **Certificate of Processing**

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

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2554435 P.O.# PO34262 Sales Order # 2367944

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 11/14/2019 09:13:54 GMT

SO Line#	Qty U	JOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	62 B	3X	100862174	Diversey Clearklens DE 900 mL	FMP19296	WO48482/DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	335 B	3X	101101081	Diversey Clearklens DE 900ml	FMP19301	WO48637/DEV002096
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	380 B	3X	7513400	Diversey Clearklens IPA 900 mL	FMP19311	WO48699/DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	3 B	3X	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19311	WO48699/DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	780 B	3X	Total			

#### **Quality Test Summary**

C	)p#	<b>Quality Test Description</b>	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
4	50.00	Minimum Dose	25.0 kGy	45.0 kGy	26.4 KGY	Pass	IWEATHERAL	11/15/2019 03:57:43 GMT
			Reason Code Test				IAN WEATHERALL	
4	50.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	IWEATHERAL	11/15/2019 03:58:07 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: ASHLEY HOBSON Date: 11/15/2019 12:36:46 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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Cianad Die

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2557203 P.O.# PO34302 Sales Order # 2371113

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 11/20/2019 04:41:27 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	860	вх	7513400	Diversey Clearklens IPA 900 mL	FMP19311	WO48699/DEV001152
	Dose Ma	р	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	45.0 kGy	27.5 KGY	Pass	JYATES	11/20/2019 17:23:13 GMT
		Reason Code Test				JOHN YATES	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.0 KGY	Pass	JYATES	11/20/2019 17:23:32 GMT
		Reason Code Test				JOHN YATES	

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: 11/22/2019 15:45:10 GMT

Reason: Work Order Completions



## **Certificate of Processing**

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Cianad Die

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2563860 P.O.# PO34342 Sales Order # 2378930

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 11/27/2019 10:46:22 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	189	вх	7513400	Diversey Clearklens IPA 900 mL	FMP19311	WO48699/DEV001152
	Dose Map	)	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	648	вх	100862174	Diversey Clearklens DE 900 mL	FMP19322	WO48698/DEV001910
	Dose Map	)	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	3	вх	100862174 Sample	Diversey Clearklens DE 900 mL	FMP19322	WO48698/DEV001910
	Dose Map	)	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	840	RY	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	27.7 KGY	Pass	DMARRIOTT DAVID MARRIOTT	11/28/2019 06:14:14 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	40.0 KGY	Pass	DMARRIOTT DAVID MARRIOTT	11/28/2019 06:14:36 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: 11/29/2019 08:25:05 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: Fmp19311 48699

Lucideon Sample Number: (196451)-49151

Lucideon Report Number: (196451)-49151/ETEP

Issue Number:

Date Logged:

27-Nov-2019

Order Number:

PO 34360

**Date Reported:** 

06-Dec-2019

Date(s) of Test(s):

01-Dec-2019 to 01-Dec-2019

**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** 

NeBoat ab-Dec-19 Mrs Natalie Boot

Senior Business Support Assistant

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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: Fmp19311 48699

Lucideon Sample Number: (196451)-49150

Lucideon Report Number: (196451)-49150/MFEP

Issue Number:

Date Logged:

27-Nov-2019

Order Number:

PO 34360

**Date Reported:** 

17-Dec-2019

Date(s) of Test(s):

28-Nov-2019 to 12-Dec-2019

**Sterility Testing** 

Membrane Filtration EP

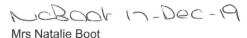
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 



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