

CERTIFICATE OF ANALYSIS

Date issue: 26 July 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23191	57760	
Production Date	10/07/2023		
Expiration Date	EXP 10/07/2025		

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	Specification	UOM	Results
Appearance	Visual	Clear Colourless Liquid	NA	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872 0.883	g/cm3	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	57760
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII	No Growth	YES	UK232893-21834
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK232893-21835

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	26/07/2023
		Natalia Traichel	26/07/2023
		Quality Control Inspector	
		Olga Kirchner	16/08/2023

The analysis results above could change over time and in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the SDS.

End of certificate of analysis

R55480102

07/17/2023 12:25:32 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3379064
P.O.#	405796			Sales Order #	3348957
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	07/15/2023 05:05:25 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	532	BX	101105062	Diversey Clearklens IPA 900ml	FMP23186	57580/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23186	57580/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	415	BX	101105062	Diversey Clearklens IPA 900ml	FMP23191	57760/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	950	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	27.5 KGY	Pass	PSAXTON	07/15/2023 14:31:20 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	PSAXTON	07/15/2023 14:31:37 GMT
		Reason Code Test				PAUL SAXTON	

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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 07/17/2023 09:52:40 GMT

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 TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

07/24/2023 10:18:16 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3380363
P.O.#	405814			Sales Order #	3350547
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/22/2023 02:48:15 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	950	BX	101105062	Diversey Clearklens IPA 900ml	FMP23191	57760/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	950	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	27.2 KGY	Pass	MFORD	07/22/2023 17:22:55 GMT
		Reason Code Test				MARTYN FORD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	MFORD	07/22/2023 17:23:17 GMT
		Reason Code Test				MARTYN FORD	

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.

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 Reason: Work Order Completions

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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3381325
P.O.#	405830			Sales Order #	3351630
25 - 45 kGy		Gamma Irradiation		Irradiation Date/Time:	07/22/2023 06:59:09 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	69	BX	101105062	Diversey Clearklens IPA 900ml	FMP23191	57760/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	6	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23191	57760/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
	75	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	27.5 KGY	Pass	MFORD	07/22/2023 17:16:54 GMT
		Reason Code Test				MARTYN FORD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.6 KGY	Pass	MFORD	07/22/2023 17:17:20 GMT
		Reason Code Test				MARTYN FORD	

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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 07/24/2023 10:17:09 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: ClearKlens IPA

Sample Description: Sample Code: Fmp23191 57760

Lucideon Sample Number: UK232893-21834

Lucideon Report Number: UK232893-21834/MFEP **Issue Number:** 1

Date Logged: 27-Jul-2023 **Order Number:** 405907

Date Reported: 16-Aug-2023 **Date(s) of Test(s):** 01-Aug-2023 to 15-Aug-2023

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

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 16 August 2023 | 12:52 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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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: ClearKlens IPA

Sample Description: Sample Code: Fmp23191 57760

Lucideon Sample Number: UK232893-21835

Lucideon Report Number: UK232893-21835/ETEP **Issue Number:** 1

Date Logged: 27-Jul-2023 **Order Number:** 405907

Date Reported: 07-Aug-2023 **Date(s) of Test(s):** 03-Aug-2023 to 03-Aug-2023

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 (<0.2000 EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot

Signing Reason: I have reviewed this document

Signing Time: 07 August 2023 | 17:01 BST

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Mrs Natalie Boot

Senior Business Support Administrator

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