

CERTIFICATE OF ANALYSIS

Date issue: 13 July 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23178	57443	
Production Date	27/06/2023		
Expiration Date	EXP 27/06/2025		

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	57443
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK232695-20394
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK232695-20395

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	13/07/2023
		Sabcho Svetoslavov	13/07/2023
		Quality Control Inspector	
		Olga Kirchner	09/08/2023

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

Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor
 TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

07/10/2023 12:15:41 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3372557
P.O.#	405679			Sales Order #	3341836
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		07/09/2023 05:05:14 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	975	BX	101105062	Diversey Clearklens IPA 900ml	FMP23178	57443/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	975	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	27.3 KGY	Pass	JATKINSON	07/09/2023 16:21:52 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.5 KGY	Pass	JATKINSON	07/09/2023 16:22:18 GMT
		Reason Code Test				JOE ATKINSON	

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: 07/10/2023 12:13:33 GMT

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 07/10/2023 12:15:33 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3373342
P.O.#	405687			Sales Order #	3343165
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/09/2023 06:54:14 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	80	BX	101105062	Diversey Clearklens IPA 900ml	FMP23178	57443/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23178	57443/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	417	BX	101105062	Diversey Clearklens IPA 900ml	FMP23182	57579/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	500	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	27.1 KGY	Pass	JATKINSON	07/09/2023 16:13:21 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.4 KGY	Pass	JATKINSON	07/09/2023 16:13:43 GMT
		Reason Code Test				JOE ATKINSON	

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
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07/04/2023 10:51:03 GMT

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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3370369
P.O.#	405653			Sales Order #	3338920
25 - 45 kGy		Gamma Irradiation		Irradiation Date/Time:	07/01/2023 07:21:48 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	596	BX	101105062	Diversey Clearklens IPA 900ml	FMP23173	57442/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23173	57442/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	376	BX	101105062	Diversey Clearklens IPA 900ml	FMP23178	57443/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	975	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	BCZAPLA	07/02/2023 04:44:04 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	BCZAPLA	07/02/2023 04:44:20 GMT
		Reason Code Test				BARTOSZ CZAPLA	

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: STEVEN WHELAN
 Reason: Work Order Completions

Date: 07/04/2023 10:50:41 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: Fmp23178 57443

Lucideon Sample Number: UK232695-20394

Lucideon Report Number: UK232695-20394/MFEP **Issue Number:** 1

Date Logged: 14-Jul-2023 **Order Number:** 405806

Date Reported: 07-Aug-2023 **Date(s) of Test(s):** 19-Jul-2023 to 02-Aug-2023

Sterility Testing

Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

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 | 16:02 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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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: Fmp23178 57443

Lucideon Sample Number: UK232695-20395

Lucideon Report Number: UK232695-20395/ETEP **Issue Number:** 1

Date Logged: 14-Jul-2023 **Order Number:** 405806

Date Reported: 02-Aug-2023 **Date(s) of Test(s):** 20-Jul-2023 to 26-Jul-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: 02 August 2023 | 15:12 BST
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Mrs Natalie Boot

Senior Business Support Administrator

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