

CERTIFICATE OF ANALYSIS

Date issue: 12 December 2022

Product Name	CLEARLENs IPA VH1		
Product Code	☒ 101105062	☐ 101105063	☐ 101105064
Batch Number	FMP22315	55930	
Production Date	11/11/2022		
Expiration Date	EXP 11/11/2024		

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	55930
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK224882-31879
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK224882-31880

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	12/12/2022
		Sabcho Svetoslavov	12/12/2022
		Quality Control Inspector	
		Olga Kirchner	24/01/2023

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

11/28/2022 13:34:58 GMT

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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3238508
P.O.#	403987			Sales Order #	3184679
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/25/2022 22:09:17 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	63	BX	101105062	Diversey Clearklens IPA 900ml	FMP22306	FMP55929
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22306	FMP55929
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	909	BX	101105062	Diversey Clearklens IPA 900ml	FMP22315	FMP55930
	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	Minimum Dose	25.0 kGy	45.0 kGy	27.8 KGY	Pass	JATKINSON	11/26/2022 17:18:11 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.8 KGY	Pass	CCICALA	11/28/2022 11:14:44 GMT
		Reason Code Test				CLAIRE CICALA	

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: 11/28/2022 13:25:43 GMT

R55480102

 12/05/2022 10:42:19 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3242795
P.O.#	404040			Sales Order #	3189777
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	12/03/2022 00:39:39 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	525	BX	101105062	Diversey Clearklens IPA 900ml	FMP22315	55930/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	25	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22315	55930/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	550	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	28.1 KGY	Pass	PSAXTON	12/03/2022 09:37:25 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	PSAXTON	12/03/2022 09:37:46 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: 12/05/2022 10:40:04 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: Fmp22315 55930

Lucideon Sample Number: UK224882-31879

Lucideon Report Number: UK224882-31879/MFEP **Issue Number:** 1

Date Logged: 13-Dec-2022 **Order Number:** 404148

Date Reported: 23-Jan-2023 **Date(s) of Test(s):** 04-Jan-2023 to 18-Jan-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

NcBook 23 JAN 23

Mrs Natalie Boot

Senior Business Support Administrator

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Flexible Medical Packaging

Unit 8
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White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp22315 55930

Lucideon Sample Number: UK224882-31880

Lucideon Report Number: UK224882-31880/ETEP **Issue Number:** 1

Date Logged: 13-Dec-2022 **Order Number:** 404148

Date Reported: 11-Jan-2023 **Date(s) of Test(s):** 05-Jan-2023 to 05-Jan-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 (<0.2000EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

Natalie Boot 11 Jan 23

Mrs Natalie Boot

Senior Business Support Administrator

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