

## CERTIFICATE OF ANALYSIS

Date issue: 14 April 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23086	56745	
Production Date	27/03/2023		
Expiration Date	EXP 27/03/2025		

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	56745
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK231381-9524
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK231381-9525

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Sabcho Svetoslavov	14/04/2023
		Justyna Staron	14/04/2023
		Quality Control Inspector	
		Olga Kirchner	10/05/2023

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

 04/11/2023 8:33:50 GMT  
 Page 1 of 1

<b>Customer Name:</b>	FLEXIBLE MED. GBP UK LANCASTER	<b>Processing Facility:</b>	Markham Vale	<b>Work Order #</b>	3319827
<b>P.O.#</b>	404950			<b>Sales Order #</b>	3280068
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	04/07/2023 10:44:07 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	447	BX	101105062	Diversey Clearklens IPA 900ml	FMP23086	56745/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23086	56745/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
	450	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	38.3 KGY	Pass	DYATES DANIEL YATES	04/08/2023 04:37:40 GMT
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.2 KGY	Pass	DYATES DANIEL YATES	04/08/2023 04:37:56 GMT
		Reason Code Test					

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  
 Reason: Work Order Completions

Date: 04/11/2023 08:33:40 GMT

R55480102

 04/11/2023 8:13:35 GMT  
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3319837
P.O.#	404951			Sales Order #	3280074
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	04/07/2023 08:43:03 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	FMP23086	56745/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	27.0 KGY	Pass	IWEATHERAL	04/07/2023 17:15:45 GMT
		Reason Code Test				IAN WEATHERALL	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.5 KGY	Pass	IWEATHERAL	04/07/2023 17:16:05 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.

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 Reason: Work Order Completions

Date: 04/11/2023 08:13:15 GMT

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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: Fmp23086 56745

**Lucideon Sample Number:** UK231381-9524

**Lucideon Report Number:** UK231381-9524/MFEP **Issue Number:** 1

**Date Logged:** 18-Apr-2023 **Order Number:** 405030

**Date Reported:** 10-May-2023 **Date(s) of Test(s):** 21-Apr-2023 to 05-May-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: 10 May 2023 | 14:38 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: Fmp23086 56745

**Lucideon Sample Number:** UK231381-9525

**Lucideon Report Number:** UK231381-9525/ETEP **Issue Number:** 1

**Date Logged:** 18-Apr-2023 **Order Number:** 405030

**Date Reported:** 03-May-2023 **Date(s) of Test(s):** 21-Apr-2023 to 22-Apr-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

Deviation during initial testing which invalidated test results. Test repeated with satisfactory results as above.  
Refer to Deviation DEV 9559.

**End of Test Report**

DocuSigned by:

*Natalie Boot*



Signer Name: Natalie Boot  
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Mrs Natalie Boot

**Senior Business Support Administrator**

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