

CERTIFICATE OF ANALYSIS

Date issue: 13/09/2022


Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	<input checked="" type="checkbox"/> 101105062/ <input type="checkbox"/> 101105063/ <input type="checkbox"/> 101105064
Batch Number	FMP22228; 55367
Production date	16/08/2022
Expiration Date	EXP 16/08/2024

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	Unit	Results
Appearance	Visual	Colourless Clear Liquid	N/A	Colourless Clear Liquid
Specific Gravity (20°C)	DM 004	0.872 - 0.883	g/cm ³	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	Yes	55367
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	Yes	UK223683 – 23845
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	Yes	UK223683 – 23846

	Date of released On behalf of Diversey's Manufacturing location: 06/10/2022	by : Olga Kirchner Position: QA Assistance
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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

08/30/2022 8:38:20 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3181939
P.O.#	403253			Sales Order #	3117844
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	08/26/2022 11:09:08 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	132	BX	101105062	Diversey Clearklens IPA 900ml	FMP22216	55366/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22216	55366/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	840	BX	101105062	Diversey Clearklens IPA 900ml	FMP22228	55367/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	Minimum Dose	25.0 kGy	45.0 kGy	27.3 KGY	Pass	MFORD	08/27/2022 00:36:37 GMT
		Reason Code Test				MARTYN FORD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.7 KGY	Pass	MFORD	08/27/2022 00:36:59 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: CLAIRESICALA
Reason: Work Order Completions

Date: 08/30/2022 08:38:00 GMT

R55480102

 09/05/2022 8:22:53 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3185983
P.O.#	403300			Sales Order #	3122786
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	09/03/2022 13:31:04 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
107.000	560	BX	101105062	Diversey Clearklens IPA 900ml	FMP22228	55367/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
108.000	15	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22228	55367/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
	575	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	39.1 KGY	Pass	LDAWSON	09/04/2022 02:56:33 GMT
		Reason Code Test				LINDSAY DAWSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	LDAWSON	09/04/2022 02:57:06 GMT
		Reason Code Test				LINDSAY DAWSON	

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: 09/05/2022 08:21:49 GMT

R55480102

10/03/2022 10:44:24 GMT

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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3203698
P.O.#	403479			Sales Order #	3143157
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	10/01/2022 18:31:39 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	325	BX	101101081	Diversey Clearklens DE 900ml	FMP22265	55569/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	24	BX	101105062	Diversey Clearklens IPA 900ml	FMP22228	55367/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	1	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22228	55367/DEV002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	350	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	IWEATHERAL	10/02/2022 12:38:56 GMT
		Reason Code Test				IAN WEATHERALL	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.5 KGY	Pass	IWEATHERAL	10/02/2022 12:39:18 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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 10/03/2022 10:40:12 GMT

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: Fmp22228 55367

Lucideon Sample Number: UK223683-23845

Lucideon Report Number: UK223683-23845/MFEP **Issue Number:** 1

Date Logged: 15-Sep-2022 **Order Number:** 403419

Date Reported: 06-Oct-2022 **Date(s) of Test(s):** 16-Sep-2022 to 30-Sep-2022

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

Natalie Boot 06 Oct-22

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: Fmp22228 55367

Lucideon Sample Number: UK223683-23846

Lucideon Report Number: UK223683-23846/ETEP **Issue Number:** 1

Date Logged: 15-Sep-2022 **Order Number:** 403419

Date Reported: 28-Sep-2022 **Date(s) of Test(s):** 25-Sep-2022 to 25-Sep-2022

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

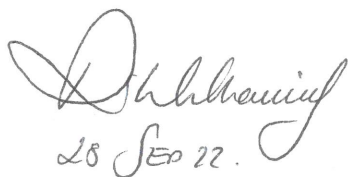
Test Results:

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



28 Sep 22.

Robin Williams

Microbiology Laboratory Supervisor

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