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## **CERTIFICATE OF ANALYSIS**

Date issue: 05/04/2022

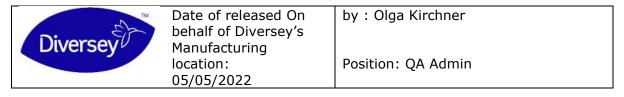
<b>Product Name</b>	DI ClearKlens IPA VH1 S 6x0.9L
<b>Product Code</b>	⊠101105062/□101105063/□101105064
<b>Batch Number</b>	FMP22066; 54490
<b>Production date</b>	07/03/2022
<b>Expiration Date</b>	EXP 07/03/2024

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/cm³	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	54490
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK221489- 9433
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK221489- 9434



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\*\*\*

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# **Certificate of Processing**

# STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102

03/21/2022 13:12:23 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3078412 P.O.# 402139 Sales Order # 2996147

**25 - 45 kGy Gamma Irradiation Irradiation Date/Time:** 03/18/2022 22:41:39 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	479 BX	100862174	Diversey Clearklens DE 900 mL	FMP22060	54178/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP22060	54178/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	69 BX	101101081	Diversey Clearklens DE 900ml	FMP22068	54180/STR002096
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	346 BX	101105062	Diversey Clearklens IPA 900ml	FMP22066	54490/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
105.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22066	54490/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	900 BX	Total			

#### **Processing Summary**

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)
400.00	Flammable Staging for Receipt	UPWHS		
405.00	Flammable External Storage	EXTERNALFLAMMABLE		
410.00	Flammable Staging for Prep	UPWHS FLAM STAGING		
420.00	Loading	LOADING		
430.00	In Process	CELL A		
440.00	Unloading	UNLOADING		
450.00	Collect Run Data	EXTERNALFLAMMABLE		

#### **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 Reason Code Test	45.0 kGy	27.6 KGY	Pass	JBARRATT JAMIE BARRATT	03/20/2022 04:48:30 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.6 KGY	Pass	JBARRATT JAMIE BARRATT	03/20/2022 04:48:51 GMT

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 Date: 03/21/2022 13:12:07 GMT

Reason: Work Order Completions

## PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: FMP22066 54490

Lucideon Sample Number: UK221489-9433

Lucideon Report Number: UK221489-9433/MFEP

Issue Number:

1

Date Logged:

07-Apr-2022

Order Number:

402354

**Date Reported:** 

03-May-2022

Date(s) of Test(s):

14-Apr-2022 to 28-Apr-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** 

Mrs Natalie Boot

Senior Business Support Administrator

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# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKens IPA

Sample Description:

Sample Code: FMP22066 54490

Lucideon Sample Number: UK221489-9434

Lucideon Report Number: UK221489-9434/ETEP

**Issue Number:** 

Date Logged:

07-Apr-2022

**Order Number:** 

402354

Date Reported:

20-Apr-2022

Date(s) of Test(s):

15-Apr-2022 **to** 15-Apr-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 (<0.2000EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report** 

MCBOOK 30-APK-22

Mrs Natalie Boot

Senior Business Support Administrator

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