

Diversey Europe BV
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www.Diversey.com
Diversey - Lets Live

### **CERTIFICATE OF ANALYSIS**

Date issue: 26/3/2024

Product Name	DI ClearKlens IPA VH1 S 6x0.9L				
<b>Product Code</b>	<b>✓</b> 101105062	□ 101105063	□ 101	105064	
<b>Batch Number</b>	FMP23311		58915		
<b>Production Date</b>	07/11/2023				
<b>Expiration Date</b>	EXP 07/11/2025				

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	on UOM	Results
Appearance	Visual	Clear Colourless L	iquid NA	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872 0.8	383 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	58915
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK234412-33453
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK234412-33454



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 recommeded conditions indicated in the SDS.

\*\*\*End of certificate of analysis\*\*\*

DocuSigned by:

Tuliana de Souza Hyczy Hamberland

—DABD7554EF0947F...

Juliana de Souza Hyczy Hamberland

Quality Programs Manager

Diversey - A Solenis Company 26/3/2024

Pharma COA Template COA Ph 01 July 2020 Page 1 of 1



## **Certificate of Processing**

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

R55480102

11/20/2023 13:49:40 GMT

Page 1 of 1

**Customer Name:** P.O.#

FLEXIBLE MED. GBP UK LANCASTER 406774

**Processing Facility:** 

Markham Vale

Work Order # Sales Order #

3448541 3430600

25 - 45 kGy

**Gamma Irradiation** 

Irradiation Date/Time:

11/17/2023 12:59:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	650	вх	101105062	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	)	302_0112	RF: 13.5A3, AF Min: 0.717		
	050	DV	T-4-1			

**Quality Test Summary** 

						Signed By	- <b>-</b>
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.3 KGY	Pass	LDAWSON	11/18/2023 00:59:18 GMT
		Reason Code Test				LINDSAY DAWSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	LDAWSON	11/18/2023 00:59:47 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: RHIANNON GATES

Reason: Work Order Completions

Date:

11/20/2023 13:46:44 GMT

TH 26/3/2024

·DS



## **Certificate of Processing**

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

R55480102

11/20/2023 13:50:28 GMT

Page 1 of 1

**Customer Name:** P.O.#

FLEXIBLE MED. GBP UK LANCASTER

406809

**Processing Facility:** 

Markham Vale

Work Order # Sales Order # 3449998 3432353

25 - 45 kGy

**Gamma Irradiation** 

Irradiation Date/Time:

11/17/2023 15:55:33 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1075	вх	101105062	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	)	302_0112	RF: 13.5A3, AF Min: 0.717		
	1075	DV	Total			

**Quality Test Summary** 

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	LDAWSON	11/18/2023 06:33:55 GMT
		Reason Code Test				LINDSAY DAWSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.2 KGY	Pass	LDAWSON	11/18/2023 06:34:26 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: RHIANNON GATES

Reason: Work Order Completions

Date: 11/20/2023 13:48:20 GMT

TH 26/3/2024

-DS



## **Certificate of Processing**

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

R55480102

11/27/2023 10:24:10 GMT

Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3456219 P.O.# 346881 Sales Order # 3439349

**25 - 45 kGy** Gamma Irradiation Irradiation Date/Time: 11/25/2023 11:42:18 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	427 BX	101105062	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23311	58915/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	395 BX	100862174	Diversey Clearklens DE 900 mL	FMP23318	58916/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	825 BX	Total			

#### **Quality Test Summary**

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	 Date /Time
	Quality Test Description	- Inniniani opco	тахітаті орсс	rtosuit	1 433/1 411		Date / Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.8 KGY	Pass	CCICALA	11/27/2023 09:20:42 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.4 KGY	Pass	DYATES	11/26/2023 01:39:23 GMT
		Reason Code Test				DANIEL YATES	

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 Date: 11/27/2023 10:23:31 GMT

Reason: Work Order Completions

□DS □#

26/3/2024

### PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

Mrs. Olga Kirchner FAO:

Report of Tests on: ClearKlens IPA

**Sample Description:** Sample Code: Fmp23311 58915

Lucideon Sample Number: UK234412-33453

Lucideon Report Number: UK234412-33453/MFEP **Issue Number:** 

**Order Number: Date Logged:** 406976 01-Dec-2023

Date(s) of Test(s): 05-Dec-2023 to 19-Dec-2023 21-Dec-2023 **Date Reported:** 

> **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: 21 December 2023 | 15:51 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

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Stoke-on-Trent, Staffordshire ST4 7LQ

Natalie.Boot@uk.lucideon.com

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Natalie.Boot@uk.lucideon.com

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**Timestamp** 

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Natalie Boot

natalie.boot@uk.lucideon.com

PlaceHolder

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Natalie Boot

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Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	21-Dec-23   15:50
Certified Delivered	Security Checked	21-Dec-23   15:50
Signing Complete	Security Checked	21-Dec-23   15:51
Completed	Security Checked	21-Dec-23   15:51
Payment Events	Status	Timestamps

### PHARMACEUTICAL ANALYSIS REPORT



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: Fmp23311 58915

Lucideon Sample Number: UK234412-33454

Lucideon Report Number: UK234412-33454/ETEP Issue Number: 1

Date Logged: 01-Dec-2023 Order Number: 406976

**Date Reported:** 14-Dec-2023 **Date(s) of Test(s):** 07-Dec-2023 **to** 07-Dec-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: 14 December 2023 | 09:53 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Signature **Signer Events Timestamp** Natalie Boot Sent: 14-Dec-23 | 09:53 Natalie Boot Viewed: 14-Dec-23 | 09:53 natalie.boot@uk.lucideon.com PlaceHolder Signed: 14-Dec-23 | 09:53 Lucideon Limited Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required), Authentication, Logged in 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.222.148

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Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	14-Dec-23   09:53
Certified Delivered	Security Checked	14-Dec-23   09:53
Signing Complete	Security Checked	14-Dec-23   09:53
Completed	Security Checked	14-Dec-23   09:53
Payment Events	Status	Timestamps