

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht, The Netherlands Tel. +31 (0)30 247 6427 www.Diversey.com Diversey - Lets Live

# **CERTIFICATE OF ANALYSIS**

Date issue: 13 November 2023

Product Name	CLEARKLENS IPA \	/H1		
Product Code	☑ 101105062	□ 101105063	□ 10	1105064
Batch Number	FMP23294		58575	
Production Date	21/10/2023			
Expiration Date	EXP 21/10/2025			

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	Speci	fication	UOM	Results
Appearance	Visual	Clear Colour	less 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	58575
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK234161-31439
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK234161-31440
Diversey	Date of released on behalf of Diversey's	Testers: Sabcho Svetoslavov Angelíka Píetraszk		13/11/2023 13/11/2023
Diversey	Manufacturing Location:	Quality Control Inspecto Olga Kírchner		05/12/2023

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 recommeded conditions indicated in the SDS.

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



# **Certificate of Processing**

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

R55480102

#### 10/30/2023 10:39:11 GMT Page 1 of 1

Customer P.O.#	r Name:	FLE 4066	XIBLE MED. GBP UK LANCASTER 520	Processing Facility:	Markham Vale	Work Order # 3440010 Sales Order # 3420528
	25 - 45 kG	9y		Gamma Irradiation	Irradiation Date/Time:	10/28/2023 18:46:39 GMT
SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	538	BX	101105062	Diversey Clearklens IPA 900ml	FMP23294	58575/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	459	BX	101105063	Clearklens IPA 900 mls	FMP23285	58574/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23285	58574/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	1000	вх	Total			

#### **Quality Test Summary**

			Quality 10	or ourman	<b>y</b>	Signed By	
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.6 KGY	Pass	JATKINSON JOE ATKINSON	10/29/2023 17:43:44 GMT
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	JATKINSON	10/29/2023 17:44:09 GMT
		Reason Code Test				JOE ATKINSON	

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: 10/30/2023 10:38:17 GMT



# **Certificate of Processing**

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

R55480102

11/06/2023 11:16:28 GMT Page 1 of 1

Customer P.O.#	Name:	FLE 4066	XIBLE MED. GBP UK LANCASTER 551	Processing Facility:	Markham Vale	Work Order # Sales Order #	3442545 3423567
	25 - 45 k	Gy		Gamma Irradiation	Irradiation Date/Time:	11/03/2023 02:13:07	GMT
SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Numbe	r
101.000	1075 Dose Mar <b>1075</b>	ВХ Э <b>ВХ</b>	101105062 302_0112 <b>Total</b>	Diversey Clearklens IPA 900ml RF: 13.5A3, AF Min: 0.717	FMP23294	58575/STR00	2199

#### **Quality Test Summary**

			Quality 10	Stoumnar	y		
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	27.7 KGY	Pass	JATKINSON JOE ATKINSON	11/04/2023 03:17:31 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.0 KGY	Pass	JATKINSON JOE ATKINSON	11/04/2023 03:18:40 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: CLAIRE CICALA Reason: Work Order Completions Date: 11/06/2023 11:08:48 GMT



# **Certificate of Processing**

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

R55480102

11/06/2023 11:17:43 GMT Page 1 of 1

Customer P.O.#	Name:	FLE2 4066	XIBLE MED. GBP UK LANCASTER 583	Processing Facility:	Markham Vale		443411 424552
	25 - 45 kG	iy		Gamma Irradiation	Irradiation Date/Time:	11/02/2023 23:49:29 GM	ИТ
SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number	
101.000	536	BX	101105062	Diversey Clearklens IPA 900ml	FMP23294	58575/STR00219	99
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717			
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23294	58575/STR00219	99
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717			
103.000	186	BX	101105062	Diversey Clearklens IPA 900ml	FMP23300	58737/STR00219	99
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717			
	725	вх	Total				

#### **Quality Test Summary**

			Quality 10	Stoummar	у		
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	28.2 KGY	Pass	JATKINSON JOE ATKINSON	11/04/2023 02:57:11 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.9 KGY	Pass	JATKINSON JOE ATKINSON	11/04/2023 02:57:37 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: CLAIRE CICALA Reason: Work Order Completions Date: 11/06/2023 11:14:49 GMT

# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

Report of Tests on:	ClearKlens IPA				
Sample Description:	Sample Code: Fmp23294	58575			
Lucideon Sample Number:	UK234161-31439				
Lucideon Report Number:	UK234161-31439/MFEP	Issue Number:	1		
Date Logged:	14-Nov-2023	Order Number:	406817		
Date Reported:	04-Dec-2023	Date(s) of Test(s):	16-Nov-2023	to	30-Nov-2023
		rility Testing ane 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** 



Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 04 December 2023 | 16:05 GMT

### Mrs Natalie Boot

#### Senior Business Support Administrator

Page 1 of 1

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# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs. Olga Kirchner

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method					
Endotoxin Test (EP)					
Date Reported:	17-Nov-2023	Date(s) of Test(s):	16-Nov-2023 <b>to</b>	16-Nov-2023	
Date Logged:	14-Nov-2023	Order Number:	406817		
Lucideon Report Number:	UK234161-31440/ETEP	Issue Number:	1		
Lucideon Sample Number:	UK234161-31440				
Sample Description:	Sample Code: Fmp23294 58575				
Report of Tests on:	ClearKlens IPA				

#### **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: 17 November 2023 | 12:56 GMT

-90369E9048134123B65D5E8FBD375BF3

#### Mrs Natalie Boot

D

#### Senior Business Support Administrator

Page 1 of 1

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Intermediary Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Editor Delivery Events	Status	Timestamp
In Person Signer Events	Signature	Timestamp