

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

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CERTIFICATE OF ANALYSIS

Date issue: 05/04/2022

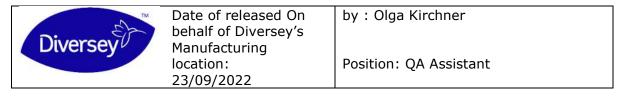
Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	⊠101105062/□101105063/□101105064
Batch Number	FMP22216; 55366
Production date	04/08/2022
Expiration Date	EXP 04/08/2024

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/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	55366
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	Yes	UK223523- 22826
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	Yes	UK223523- 22827



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

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08/15/2022 9:11:09 GMT Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3174705 P.O.# 403177 Sales Order # 3109123

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 08/13/2022 17:23:58 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	523 BX	100862174	Diversey Clearklens DE 900 mL	FMP22213	55365/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP22213	55365/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	349 BX	101105062	Diversey Clearklens IPA 900ml	FMP22216	55366/STR002199
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	875 BX	Total			

Quality Test Summary

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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	26.3 KGY	Pass	JYATES JOHN YATES	08/14/2022 04:11:54 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	37.6 KGY	Pass	JYATES JOHN YATES	08/14/2022 04:12:12 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: 08/15/2022 09:10:59 GMT

Reason: Work Order Completions



Certificate of Processing

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08/22/2022 8:48:28 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3178888 P.O.# Sales Order # 3114087

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 08/20/2022 18:58:00 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 950 ВХ 101105062 Diversey Clearklens IPA 900ml FMP22216 55366/STR002199 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 вх 950 Total

Quality Test Summary

						Signed by	•
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.2 KGY	Pass	SWARD	08/21/2022 05:02:10 GMT
		Reason Code Test				SIMON WARD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	SWARD	08/21/2022 05:02:39 GMT
		Reason Code Test				SIMON WARD	

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: 08/22/2022 08:36:11 GMT

Reason: Work Order Completions



Certificate of Processing

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08/30/2022 8:38:20 GMT Page 1 of 1

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	User	Date /Time
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.3 KGY	Pass	MFORD MARTYN FORD	08/27/2022 00:36:37 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	38.7 KGY	Pass	MFORD MARTYN FORD	08/27/2022 00:36:59 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 Date: 08/30/2022 08:38:00 GMT

Reason: Work Order Completions

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp22216 55366

Lucideon Sample Number: UK223523-22826

Lucideon Report Number: UK223523-22826/MFEP

Issue Number:

Date Logged:

02-Sep-2022

Order Number:

403331

Date Reported:

22-Sep-2022

Date(s) of Test(s):

04-Sep-2022 to 18-Sep-2022

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



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:

Sampl Code: Fmp22216 55366

Lucideon Sample Number: UK223523-22827

Lucideon Report Number: UK223523-22827/ETEP

Issue Number:

Date Logged:

02-Sep-2022

Order Number:

403331

Date Reported:

15-Sep-2022

Date(s) of Test(s):

09-Sep-2022 to 09-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

Microbiology Laboratory Supervisor

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