



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 23.08.2019

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 19178 47944
Production Date	27.06.2019
Expiration Date	EXP 27/06/2021

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	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		clear colourless liquid
Specific Gravity (20°C)	DM004	0.872	0.883	0.877

On behalf of Diversey site Quality Manager	Name :	J. Sluiter
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
--------------	--------------	--

R55480102

 09/10/2019 11:32:54 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2508562
P.O.#	PO33822			Sales Order #	2315800
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	09/08/2019 07:42:17 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	445	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	430	BX	101100418	Diversey Clearkens IPA/DE 900	FMP19191	WO47716 / DEV002080
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5	BX	101100418_SAMPLE	Diversey Clearkens IPA/DE 900	FMP19191	WO47716 / DEV002079
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	880	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	ESILLS	09/10/2019 11:29:21 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	45.1 KGY	Fail	IWEATHERAL	09/09/2019 09:11:00 GMT
		Reason Code Test				IAN WEATHERALL	

The above products were not processed according to the process specification requirements. Some parameters reviewed were found not to be in compliance with specifications as indicated on attached nonconformance document(s).

Please refer to DEF-10122. Maximum dose achieved is over the Customer Specification. Incorrect dosimeter placement during processing run. Minimum dose calculated using ratio factors.

Electronically Signed By: EMMA SILLS
 Reason: Work Order Completions

Date: 09/10/2019 11:32:08 GMT

R55480102

 07/26/2019 13:50:11 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2482230
P.O.#	PO33409			Sales Order #	2284145
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/24/2019 22:47:27 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	435	BX	100862174	Diversey Clearklens DE 900 mL	FMP19129	WO47422 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	704	BX	7514372	Diversey Clearklens IPA 900 mL	FMP19138	WO47179 / DEV001250
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5	BX	7514372 Sample	Diversey Clearklens IPA 900 mL	FMP19138	WO47179 / DEV001250
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	265	BX	100862174	Diversey Clearklens DE 900 mL	FMP19142	WO47428 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
105.000	5	BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP19142	WO47422 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
109.000	2	BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP19129	WO47922 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
110.000	5	BX	7514372	Diversey Clearklens IPA 900 mL	FMP19138	WO47179 / DEV001250
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
111.000	5	BX	100862174	Diversey Clearklens DE 900 mL	FMP19142	WO47428 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
112.000	14	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	1440	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	28.6 KGY	Pass	EBROWN	07/26/2019 11:37:42 GMT
		Reason Code Test				EMMA BROWN	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	41.8 KGY	Pass	EBROWN	07/26/2019 11:37:58 GMT
		Reason Code Test				EMMA BROWN	

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 BROWN
 Reason: Work Order Completions

Date: 07/26/2019 13:49:25 GMT

R55480102

 08/02/2019 11:33:09 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2485513
P.O.#	PO33410			Sales Order #	2288022
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/29/2019 15:27:51 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	432	BX	100862174	Diversey Clearklens DE 900 mL	FMP19142	WO47428 / DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	972	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19144	WO47430 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5	BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19144	WO47430 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	11	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	1420	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	41.2 KGY	Pass	SWARD	07/30/2019 17:41:15 GMT
		Reason Code Test				SIMON WARD	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.6 KGY	Pass	EBROWN	07/31/2019 07:31:18 GMT
		Reason Code Test				EMMA BROWN	

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 BROWN
 Reason: Work Order Completions

Date: 07/31/2019 07:35:16 GMT

R55480102

07/31/2019 13:03:27 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2485519
P.O.#	PO33411			Sales Order #	2288026
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/30/2019 16:36:09 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	449	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19144	WO47430 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	972	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19150	WO47307 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	19	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	1440	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	41.0 KGY	Pass	JATKINSON	07/31/2019 12:47:18 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.3 KGY	Pass	EBROWN	07/31/2019 12:59:59 GMT
		Reason Code Test				EMMA BROWN	

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 BROWN
Reason: Work Order Completions

Date: 07/31/2019 13:02:48 GMT

R55480102

 08/16/2019 12:48:08 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2482757
P.O.#	PO33412			Sales Order #	2296724
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	08/14/2019 23:32:19 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	453	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19150	WO47307 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	707	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19176	WO47636 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5	BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19176	WO47636 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	216	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
105.000	5	BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
106.000	5	BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP19150	WO47307 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
109.000	4	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19178	NA
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
110.000	5	BX	FMP Dunnage Boxes	Customer Supplied	NA	NA
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	1400	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	29.2 KGY	Pass	ESILLS	08/16/2019 12:35:33 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	43.2 KGY	Pass	ESILLS	08/16/2019 12:35:51 GMT
		Reason Code Test				EMMA SILLS	

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
 Reason: Work Order Completions

Date: 08/16/2019 12:47:26 GMT

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Alison Siddle

Report of Tests on: Clearklens IPA FMP19178

Sample Description: 47944

Lucideon Sample Number: (194869)-37739

Lucideon Report Number: (194869)-37739/ETEP **Issue Number:** 1

Date Logged: 02-Sep-2019 **Order Number:** PO33824

Date Reported: 11-Sep-2019 **Date(s) of Test(s):** 10-Sep-2019 to 10-Sep-2019

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 (<0.2 EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

Nat Boot 11 Sep-19

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1980455.

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

Insight creating advantage

Flexible Medical Packaging
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Alison Siddle

Report of Tests on: Clearklens IPA FMP19178

Sample Description: 47944

Lucideon Sample Number: (194869)-37738

Lucideon Report Number: (194869)-37738/MFEP **Issue Number:** 1

Date Logged: 02-Sep-2019 **Order Number:** PO33824

Date Reported: 20-Sep-2019 **Date(s) of Test(s):** 04-Sep-2019 to 18-Sep-2019

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

NOBOK 20 Sep - 19

Mrs Natalie Boot
Senior Business Support Assistant

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1980455.

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com