Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 22/07/2019

Product Name	**CLEARKLENS IPA VH1**
Product Code	75134 00
Batch Number	EMP 19134 47306
Production Date	14/05/2019
Expiration Date	EXP 14/05/2021

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 Lower - Upper	Results
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 :	Bartyzel, J. Slavan
	Position	Quality Control Inspector

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

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON
insight creating advantage

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

FAO: Ms. Alison Siddle

Report of Tests on: Clearklens IPA

Sample Description: Sample Code: FMP19134 47306

Lucideon Sample Number: (194099)-32587

Lucideon Report Number: (194099)-32587/ETEP **Issue Number:** 1

Date Logged: 23-Jul-2019 **Order Number:** PO 33520, PO 33569

Date Reported: 02-Aug-2019 **Date(s) of Test(s):** 25-Jul-2019 to 25-Jul-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 <0.2EU/ml

Tests carried out in accordance with cGMP

End of Test Report

NBoot 02-Aug-19
Mrs Natalie Boot
Senior Business Support Assistant

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

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enquiries@lucideon.com
www.lucideon.com

PHARMACEUTICAL ANALYSIS REPORT

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LA1 4XS

FAO: Ms. Alison Siddle

Report of Tests on: Clearklens IPA

Sample Description: Sample Code: FMP19134 47306

Lucideon Sample Number: (194099)-32586

Lucideon Report Number: (194099)-32586/MFEP **Issue Number:** 1

Date Logged: 23-Jul-2019 **Order Number:** PO 33520, PO 33569

Date Reported: 12-Aug-2019 **Date(s) of Test(s):** 25-Jul-2019 to 08-Aug-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

12-AUG-19

Mrs Andrea Saunders
Business Support Assistant

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

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www.lucideon.com

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3998A

Product Code	Lot Number	Quantity	UOM
DIVER DE BLK2 BOTTLE DV4648	FMP19134 47306	216	Case
Validation Reference Number: 4648			
DIVER DE BLK2 BOTTLE DV4648	FMP19134 47306, INC 5 SMPLS	5	Case
Validation Reference Number: 4648			

Processing Run Start Date: 05-Jul-19 08:58 PM

Processing Run End Date: 06-Jul-19 06:13 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**27.3**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**40.4**

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

Sterigenics.
A Sotera Health company

Certificate of Processing

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

R55480102

Customer Name: FLEXIBLE MED. GBP UK LANCASTER
P.O.# PO33408

Processing Facility: Markham Vale

Work Order # 2482220
Sales Order # 2284135

25 - 45 kGy

Gamma Irradiation

Irradiation Date/Time: 07/23/2019 21:25:11 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1127	BX	7513400	Diversey Clearklens IPA 900 mL	FMP19134	WO47306/DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	265	BX	100862174	Diversey Clearklens DE 900 mL	FMP19129	WO47422/DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
107.000	3	BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP19129	WO47422/DEV001910
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
108.000	5	BX	100862174	Diversey Clearklens DE 900 mL	FMP19129	WO47422/DEV001910
	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	Signed By - Date /Time
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	41.3 KGY	Pass	PSAXTON PAUL SAXTON	07/24/2019 19:07:20 GMT
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	28.3 KGY	Pass	EBROWN EMMA BROWN	07/26/2019 07:53:10 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 BROWN
Reason: Work Order Completions

Date: 07/26/2019 08:52:04 GMT