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CERTIFICATE OF ANALYSIS

Date: 22/07/2019

Product Name	**CLEARKLENS DE VH29**
Product Code	7515783
Batch Number	FMP19128 47283
Production Date	08/05/2019
Expiration Date	EXP 08/05/2021

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	0.880 0.888	0.885

On behalf of Diversey site Quality Manager	Name :	Rutyusko J. Slavo
	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

FAO: Ms. Alison Siddle

Report of Tests on:	Clearklens DE		
Sample Description:	Sample Code: FMP19128 47283		
Lucideon Sample Number:	(194099)-32584		
Lucideon Report Number:	(194099)-32584/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

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PHARMACEUTICAL ANALYSIS REPORT

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

FAO: Ms. Alison Siddle

Report of Tests on: Clearklens DE

Sample Description: Sample Code: FMP19128 47283

Lucideon Sample Number: (194099)-32585

Lucideon Report Number: (194099)-32585/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

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Staffordshire ST4 7LQ

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3884A

Product Code	Lot Number	Quantity	UOM
DIVER DE BLK2 BOTTLE DV4648	FMP19128 47283	432	Case

Validation Reference Number: 4648

Processing Run Start Date: 05-Jul-19 06:04 PM

Processing Run End Date: 06-Jul-19 03:44 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.1**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**41.6**

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3997A

Product Code	Lot Number	Quantity	UOM
DIVER DE BLK2 BOTTLE DV4648	FMP19128 47283	112	Case

Validation Reference Number: 4648

Processing Run Start Date: 05-Jul-19 08:23 PM

Processing Run End Date: 06-Jul-19 04:18 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.9**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**42.1**

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3758A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19128, 47283	162	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19128, 47283 5 X SAMPLES	5	Case
Validation Reference Number: 4648			

Processing Run Start Date: 03-Jul-19 07:12 AM

Processing Run End Date: 03-Jul-19 04:35 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**27.7**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**40.5**

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

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