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CERTIFICATE OF ANALYSIS

Date: 22/05/2019

Product Name	CLEARKLENS DE VH29
Product Code	100862174
Batch Number	FMP 19108 47105
Production Date	18/04/2019
Expiration Date	EXP 18/04/2021

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	0.880	0.888	0.885

On behalf of Diversey site Quality Manager	Name :	Patty S. J. Staan
	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
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3286A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
DIVER DE BLK2 BOTTLE DV4648	FMP19108 47105	162	Case
Validation Reference Number: 4648			

Processing Run Start Date: 27-May-19 11:25 PM

Processing Run End Date: 28-May-19 07:30 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.6
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.2

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: 2173-3112A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
DIVER DE BLK2 BOTTLE DV4648	FMP19108 47105	540	Case
Validation Reference Number: 4648			
DIVER DE BLK2 BOTTLE DV4648	FMP19108 47105, INC 5 SMPLS	5	Case
Validation Reference Number: 4648			

PO Number: PO33081

Processing Run Start Date: 13-May-19 02:52 PM

Processing Run End Date: 14-May-19 01:44 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	26.9
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	42.1

Other Information

FMP19108 47105, INC 5 SMPLS, 10 PLTS

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

PHARMACEUTICAL ANALYSIS REPORT



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: FMP19108 47105 Batch Ref: 10168

Lucideon Sample Number: (193742)-30422

Lucideon Report Number: (193742)-30422/MFEP Issue Number: 1

Date Logged: 03-Jul-2019 Order Number: PO33406

Date Reported: 02-Aug-2019 Date(s) of Test(s): 18-Jul-2019 to 01-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

Natalie Boot 02-Aug-19

Mrs Natalie Boot

Senior Business Support Assistant

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PHARMACEUTICAL ANALYSIS REPORT



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: FMP19108 47105 Batch Ref: 10168

Lucideon Sample Number: (193742)-30421

Lucideon Report Number: (193742)-30421/ETEP

Issue Number: 1

Date Logged: 03-Jul-2019

Order Number: PO33406

Date Reported: 22-Jul-2019

Date(s) of Test(s): 15-Jul-2019 to 15-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: <0.2 EU/ml

Tests carried out in accordance with cGMP

End of Test Report

Nat Boot 22-Jul-19

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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