

Diversey Europe Operations BV Maarasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 22/05/2019

<b>Product Name</b>	CLEARKLENS DE VH29		
Product Code			
Batch Number	FHP 19108 47105		
<b>Production Date</b>	1810412019		
<b>Expiration Date</b>	EXP 18 104 12021		

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

est Test Method		Test	Limits Lower - Upper		Results
Appearance	Visual	Clear Colourless Liquid		clear Colour- -less Liquid	
Specific Gravity (20°C)	DM004	0.880	0.888	0.885	

On behalf of Diversey site Quality Manager	Name:	Partysist 4. Stavon
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 2017
con remplace	7 ET31011 . UZ	Date of issuing . November 24 2017

**STERIS: Gamma Certificate Of Processing** 

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3286A

Product CodeLot NumberQuantityUOMDIVER DE BLK2 BOTTLE DV4648FMP19108 47105162Case

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

Product Code Lot Number Quantity UOM
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

Document ID: 20798

Last Revised in Rei 2.0.0.0

Rel Date: 08/13/2018

Page 1 of 1

## PHARMACEUTICAL ANALYSIS REPORT



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

Ms. Alison Siddle FAO:

Report of Tests on:

Clearkiens DE

Sample Description:

Sample Code: FMP19108 47105 Batch Ref: 10168

Lucideon Sample Number: (193742)-30422

Lucideon Report Number: (193742)-30422/MFEP

Issue Number:

**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** 

Senior Business Support Assistant

NOBOOK CZ-AUG-19

Page 1 of 1

# 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

lesue 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

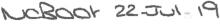
**Test Results:** 

The test results meet the EP/USP criteria: Yes

Result: <0.2 EU/mi

Tests carried out in accordance with cGMP

**End of Test Report** 



Mrs Natalie Boot

Senior Business Support Assistant

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