



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 27/02/2018

Product Name	CLEARKLENS DE VH29
Product Code	7515783
Batch Number	FMP 18038 44459
Production Date	07/02/2018
Expiration Date	EAP 07/02/2020

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	0.888

On behalf of Diversey site Quality Manager	Name :	Barlyis, J. Stanon
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
--------------	--------------	--



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 28 Feb 2018  
**Date Tested:** 05 Mar 2018  
**Date Test Completed:** 05 Mar 2018  
**Purchase Order:** 30588

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0041180/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 28/02/2018  
**Test Article:** Clearklens DE  
**Sample Code:** FMP18038 44459  
**Batch Ref:** 9082  
**Qty Received:** 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	83 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.3 2.6.14, USP 40 <85> & JPXVII
Product Standard Data Sheet	FG047/psd	FM01-01

Approval is provided by Electronic Signature. Their name and position is shown below.

BSc, CBiol, MRSB

Date: 06 Mar 2018 09:42:49

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 28 Feb 2018  
**Date Tested:** 08 Mar 2018  
**Date Test Completed:** 22 Mar 2018  
**Purchase Order:** 30588

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0041180/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 28/02/2018  
**Test Article:** Clearklens DE  
**Sample Code:** FMP18038 44459  
**Batch Ref:** 9082  
**Qty Received:** 20 x 900mL Bottles + 2 Spare

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM03

### Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias

Approval is provided by Electronic Signature. Their name and position is shown below.

CBO: MKSB

Date: 23 Mar 2018 15:56:07

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology


<http://www.steris-ast.com>

# Certificate of Irradiation

Date Issued: 20-Feb-2018

UK33S12061207-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd  
Unit 8, White Cross Ind Estate  
Hightown  
Lancaster  
Lancashire LA1 4XS  
UNITED KINGDOM

All in accordance with current Technical Agreement

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106483
Customer Reference Number:	P030498
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	438
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18038 44459, 8 PLTS, Includes 6 Sample Boxes

## Irradiation Data

Date and Time of Irradiation:	20-Feb-2018 08:02
Reference Dose Range kGy:	34.1 - 36.6
Calculated Minimum Dose kGy:	26.9
Calculated Maximum Dose kGy:	41.4

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

A2

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 28-Feb-2018

UK33S12064610-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd  
Unit 8, White Cross Ind Estate  
Hightown  
Lancaster  
Lancashire LA1 4XS  
UNITED KINGDOM

All in accordance with current Technical Agreement

---

### Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106483
Customer Reference Number:	P030528
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	272
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18038 44459, 5 PLTS

---

### Irradiation Data

Date and Time of Irradiation:	27-Feb-2018 21:04
Reference Dose Range kGy:	35.2 - 37.1
Calculated Minimum Dose kGy:	27.8
Calculated Maximum Dose kGy:	42.0

---

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

---

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069