

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 19.07.2019

Product Name	CLEARKLENS DE VH29
Product Code	100862174
Batch Number	FMP 18165, 452 83
Production Date	14/06/2018
Expiration Date	EXP 14/06/2020

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
Specific Gravity (20°C)	DM004	0.880 0.888	0.884

	On behalf of Diversey site Quality Manager	Name:	Maraburda Partyusto
		Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 09-Jul-2018

UK33S12125098-2-1

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:** P031249 **Product Description: DIVER DE BLK2 BOTTLE DV4648 25-45kGy** Validation Reference: 4648 **Quantity Received:** 705 **Customer Minimum Specification kGy:** 25,0 **Customer Maximum Specification kGv:** 45.0 **Customer Unit Lot/Batch Number:** FMP18165 45283, INC 5 SMPLS, 13 PLTS **Irradiation Data** Date and Time of Irradiation: 02-Jul-2018 17:03 Reference Dose Range kGy: 35.9 - 36.9 28.4 Calculated Minimum Dose kGy: Calculated Maximum Dose kGy: 41.8

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



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: +44(0)1329 226600 +44(0)1329 226688 Fax:

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

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 **Hightown**

White Cross Industrial Estate

Lancaster **LA14XS**

Date Received:

20 Jul 2018

Date Tested:

25 Jul 2018

Date Test Completed:

08 Aug 2018

Purchase Order:

PO31421

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0043814/1

Test Required:

Sterility by Membrane Filtration Steritest

Date Received: Test Article:

20/07/2018

Clearklens DE FMP18165 45283

Sample Code: **Batch Ref:**

9437

Qty Received:

20 x 900mL Bottles + 3 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	See external comments
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.

Mary

CBick MIKSB

Date: 08 Aug 2018 16:04:51

Mrs C Moore

Page 1 of 1

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0043814 Print Number: P0052624







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 LA14XS

Date Received:

20 Jul 2018

Date Tested:

24 Jul 2018

Date Test Completed:

24 Jul 2018

Purchase Order:

PO31421

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0043814/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL

Date Received: **Test Article:** Sample Code:

20/07/2018

Clearklens DE FMP18165 45283

Batch Ref:

9437

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	93 %
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 41 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM01-01

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

24 7

CBio MRSB

Date: 25 Jul 2018 15:25:05

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0043814 Print Number: P0052310 Page 1 of 1

