



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 15.07.2018

Product Name	CLEARKLENS DE VH29
Product Code	100862174
Batch Number	FMP 16160 40621
Production Date	08/06/2016
Expiration Date	EXP 08/06/2018

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)	JDM004	0.880	0.888	0.884

On behalf of Diversey site Quality Manager	Name :	<i>Polydisia, H. H. H.</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7515783	Version : 04	Date of issuing : April 27 th 2012
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Solutions in Healthcare Contract
Manufacture & Packing

VAT Registration No: GB 534 5276 43

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

☎ 01524 68737
☎ 01524 67110
✉ sales@flexible-medical.com
🌐 www.flexible-medical.com

CERTIFICATE OF CONFORMANCE



TO:
Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

Page : 1

DATE : 15/07/16
DESPATCH NO : DN36474
FMP ORDER NUMBER : SO27961
CUSTOMER REFERENCE : 4701847174/100862174

LINE	PART NUMBER	CUSTOMER REFERENCE	QUANTITY	UNIT	LOT REF	LOT LINE
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1	DEV001910	100862174	698	EA	WO40621	
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CUSTOMER: DIVERSEY
PRODUCT: DE 900MLS BAG IN BOTTLE - CASES OF 6
BATCH NO: FMP16160 40621
PRODUCT REF: SKU 100862174
Labelled with UN LQ
ENVIROWASTE - 6 UNIT CASE - 568.5G - PLASTIC
CERTIFICATE OF ANALYSIS COMPLETE
IRRADIATION CERTIFICATE
STERILITY RESULTS REC'D

CERTIFICATE OF CONFORMANCE

These goods have been manufactured in accordance with FMP Quality Systems (ISO9001:2008, ISO13485:2003, ISO14001:2004) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: *C. Agioe*

DATE: 19/07/16





<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 09-Jul-2016

UK32S11646444-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 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:	1002733
Customer Reference Number:	P026738
Product Description:	JD DE 900ML BOTTLES 25-45kGy
Validation Reference:	4.1756
Quantity Received:	702
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/NO FMP16160 40621 THUR 16TH JUNE 2016 13 PLTS + 4 SAMPLES LOT 2

Irradiation Data

Date and Time of Irradiation:	09-Jul-2016 06:40
Reference Dose Range kGy:	36.2 - 37.7
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	40.8

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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



Wickham Laboratories

Contract Analytical Services

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

Date Received: 14 Jul 2016
Date Tested: 18 Jul 2016
Date Test Completed: 18 Jul 2016
Purchase Order: 26935

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029960/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 14/07/2016
Test Article: ClearKlens DE
Sample Code: FMP16160 40621
Batch Ref: 7675
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	75 %
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 8.0 2.6.14, USP 39 <85> & JPXVI 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 19 Jul 2016 12:44:18

Mr K.A. Barker
Business Manager – Projects

Certificate of Analysis - OSMM
Consignment: 0029960
Print Number: P0036131
Page 1 of 1



Company Registered in England No. 752951



Wickham Laboratories

Contract Analytical Services

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

Date Received: 14 Jul 2016
Date Tested: 19 Jul 2016
Date Test Completed: 02 Aug 2016
Purchase Order: 26935

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029960/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 14/07/2016
Test Article: ClearKlens DE
Sample Code: FMP16160 40621
Batch Ref: 7675
Qty Received: 20 x 900mL Bottles + 1 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.

Date: 03 Aug 2016 14:32:58

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology