



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 18.09.14

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	FMP 14251 36964
Production Date	09 / 2014
Expiration Date	09 / 2016

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		Clean Colourless Liquid
Specific Gravity (20°C)	JDM004	0.872	0.883	0.875

On behalf of Diversey site Quality Manager	Name :	Opakinchna, Madene
	Position	Quality Control Inspector

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

COA 7514372	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 12-Sep-2014

UK32S11236536-1-1

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

EN ISO 11137-1:2006 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:	1002734
Customer Reference Number:	P022930
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1723
Quantity Received:	705
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	349 X B/NO.FMP14247 36620,348 X B/NO.FMP14251 36964 + 8 SAMPLES THUR 11.09.14 14 PLTS LOT 2

## Irradiation Data

Date and Time of Irradiation:	12-Sep-2014 00:20
Reference Dose Range kGy:	36.6 - 38.8
Calculated Minimum Dose kGy:	25.8
Calculated Maximum Dose kGy:	41.5

Irradiation Release Authorised By Synergy Health plc

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



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

**Date Received:** 22 Sep 2014  
**Date Tested:** 23 Sep 2014  
**Date Test Completed:** 23 Sep 2014  
**Purchase Order:** 22986

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0018736/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 22/09/2014  
**Test Article:** CLEARLENs IPA BLOCK 2  
**Sample Code:** 5870  
**Batch Ref:** FMP14251 36964  
**Qty Received:** 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	112 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM02

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 24 Sep 2014 15:38:39

Mrs S.L. Wood  
Senior Laboratory Manager - Pharmaceutical Microbiology





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

**Date Received:** 22 Sep 2014  
**Date Tested:** 26 Sep 2014  
**Date Test Completed:** 10 Oct 2014  
**Purchase Order:** 22986

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0018736/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 22/09/2014  
**Test Article:** CLEARKLENS IPA BLOCK 2  
**Sample Code:** 5870  
**Batch Ref:** FMP14251 36964  
**Qty Received:** 21 x 900mL Bottles

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
Product Standard Data Sheet	FG047/psd	FM03

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 13 Oct 2014 17:32:48

Mrs S.L. Wood  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0018736

Certificate of Analysis - OSMM

Print Number: P0023086

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ISO  
17025

GLP GMP FDA

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