

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 09-Jun-2013 UK32S11025517-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products

ISO 9001:2008 Quality Management System

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

Customer Reference Number:	P020493
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.0615
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/No.W034151 - CUSTOMER B/No.34151 , 1 PLT LOT 1 THURS 23.5.13
Shop Order Number:	S11025517-1-1
Synergy Health Sales Part Reference:	1002720

Irradiation Data		
Date and Time of Irradiation:	09-Jun-2013 15:18	
Reference Dose Range kGy:	35.1 - 35.3	
Calculated Minimum Dose kGy:	28.9	
Calculated Maximum Dose kGy:	36.5	

Items Irradiated under WO34151 will be used in finished product batch code FMP13178 34154

E. Cravayon 29.06.13.



Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 27/6/13

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	7516431
Batch Number	FMP13178 34154
Production Date	06/2013
Expiration Date	12/2014

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	Lin Lower -	nits Upper	Results
Appearance	Visual		ntly Yellow uid	der stigette
pH (100% 20°C)	JDM001	9.0	11.4	10.7
Specific Gravity (20°C)	JDM004	0.990	1.010	1.001

On behalf of Diversey site Quality Manager	Name :	CRESCOE, A. Mafuno
	Position	Quality Control Inspector

This document being issued e	lectronically does not bear a signature	
COA 7516431	Version: 04	Date of issuing: November 28th 2011
		Dute of issuing. November 20 2011



Wickham Laboratories Limited,

Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: +44(0)1329 226600 +44(0)1329 832511

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:

01 Jul 2013

Date Tested:

09 Jul 2013

Date Test Completed:

23 Jul 2013

Purchase Order:

20639

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0011062/1

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

01/07/2013

Date Received: Test Article:

Clearkiens Cleansinald SS Block

Sample Code:

Batch Ref: Qty Received: FMP13178 34154

20 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	FM06
o 1		

Comments

Test carried out according to current Pharmacopoeias.

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

Ens Love

Date: 24 Jul 2013 13:31:05

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0011062

Certificate of Analysis - OSMM

Print Number: P0012231

Page 1 of 1