


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

Certificate of Irradiation

Date Issued: 05-Mar-2018

UK33S12064610-2-1

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:	1111497
Customer Reference Number:	P030528
Product Description:	C/SINALD BOTTLES/CAPS/BAGS DV4894 25-40KGS
Validation Reference:	4894
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO44724, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	05-Mar-2018 14:49
Reference Dose Range kGy:	33.9 - 34.0
Calculated Minimum Dose kGy:	30.9
Calculated Maximum Dose kGy:	37.3

Items irradiated under WO44724, will be used in finished product batch FMP18086 44721

C Pascoe

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



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 29.03.2018

Product Name	CLEARLENs CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 18086 44721
Production Date	27/03/2018
Expiration Date	EXP 27/03/2020

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 Slightly Yellow Liquid		Clear Slightly Yellow Liquid
pH (neat solution)	DM001	12.0	13.0	12.7
Specific Gravity (20°C)	DM004	1.040	1.060	1.048

On behalf of Diversey site Quality Manager	Name :	Pantjiste, Harshada
	Position	Quality Control Inspector

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Wickham Laboratories

Contract Analytical Services

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LA1 4XS

Date Received: 05 Apr 2018
Date Tested: 13 Apr 2018
Date Test Completed: 27 Apr 2018
Purchase Order: 30746

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0041873/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 05/04/2018
Test Article: Cleansinald SC
Sample Code: FMP18086 44721
Batch Ref: 578406
Qty Received: 20 x ~25mL bottles & 5 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 25 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	FM06

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

 BSc, CSci, MRSB

Date: 27 Apr 2018 18:23:47

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