



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 25.10.2018

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FHP18298, 46089
Production Date	25/10/2018
Expiration Date	EXP 25/04/2020

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	9.0	11.4	10.7
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name :	Harabuda, Pantyus
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



Wickham Laboratories

Contract Analytical Services

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
LA1 4XS

Date Received: 31 Oct 2018
Date Tested: 14 Nov 2018
Date Test Completed: 28 Nov 2018
Purchase Order: 32019

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0045551/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 31/10/2018
Test Article: ClearKlens Cleansinald SS
Sample Code: FMP18298 46089
Batch Ref: 9690
Qty Received: 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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM06-01

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.

 CMO: MRSB

Date: 29 Nov 2018 14:48:40

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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

Certificate of Irradiation

Date Issued: 30-Sep-2018

UK33S12172913-2-2

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:	1105380
Customer Reference Number:	P031825
Product Description:	C/SINALD SS 900ml Bottle DV4673 25-40kGy
Validation Reference:	4673
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO46090, 1 PLT

Irradiation Data

Date and Time of Irradiation:	30-Sep-2018 10:21
Reference Dose Range kGy:	32.1 - 33.4
Calculated Minimum Dose kGy:	29.4
Calculated Maximum Dose kGy:	36.5

Items irradiated under WO46090, will be used in finished product batch FMP18298 46089

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