



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 14.10.2015

Product Name	CLEARLENSS CLEANSEALD SS VH9S
Product Code	7516431
Batch Number	FMP 15286 39092
Production Date	13/10/2015
Expiration Date	13/04/2017

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 (100% 20°C)	JDM001	9.0	11.4	10.1
Specific Gravity (20°C)	JDM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	A. Paulijns, J. Slawon
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516431	Version : 04	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-Sep-2015

UK32S11468823-1-1

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:	1002720
Customer Reference Number:	P025123
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.1909
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	FMP BATCH NO: WO39091 THURS 17TH SEPT 2015 1 PLT LOT 4

Irradiation Data

Date and Time of Irradiation:	26-Sep-2015 09:33
Reference Dose Range kGy:	35.1 - 35.4
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	37.9

Items Irradiated under WO39091 will be used in finished product batch number FMP15286 39092

EGauger 14-10-15

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

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Ms D Henderson
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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 15 Oct 2015
Date Tested: 21 Oct 2015
Date Test Completed: 04 Nov 2015
Purchase Order: 25300

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025307/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 15/10/2015
Test Article: Cleansinald SS
Sample Code: FMP15286 39092
Batch Ref: 6996
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
Product Standard Data Sheet	FG047/psd	FM06

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: 05 Nov 2015 16:01:37

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology