



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26/7/13

Product Name	CLEARKLENS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	KMP13194 34689
Production Date	07/2013
Expiration Date	01/2015

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	7.3	8.2	7.4
Specific Gravity (20°C)	JDM004	0.990	1.010	0.997

On behalf of Diversey site Quality Manager	Name :	C. ASCOE D. Kuchner
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516427	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 22-Oct-2013

UK32S11065143-1-1

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:	1035147
Customer Reference Number:	P020751
Product Description:	TEGO 2000SS BLK1 25-45KGY
Validation Reference:	4.0621
Quantity Received:	64
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	59 X B/NO. FMP13194 34689 + 5 SAMPLES, 2PLTS LOT 2 THURS 18.07.13
Other Process Details:	Product labeled as S11037610-1-1, Ref customer complaint: 29218.

Irradiation Data

Date and Time of Irradiation:	22-Oct-2013 10:29
Reference Dose Range kGy:	36.8 - 37.2
Calculated Minimum Dose kGy:	26.5
Calculated Maximum Dose kGy:	39.4

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



Wickham Laboratories

contract analytical services

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

Date Received: 29 Jul 2013
Date Tested: 15 Aug 2013
Date Test Completed: 05 Sep 2013
Purchase Order: 20798

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0011557/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP
Date Received: 29/07/2013
Test Article: TEGO 2000SS Block 1
Sample Code: -
Batch Ref: FMP13194 34689
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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Growth of Sub-culture in Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in two broths
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

Comments

As Steritest Sterility Test

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

Suz Wood

Date: 05 Sep 2013 17:46:58

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0011557

Certificate of Analysis - OSMM

Print Number: P0013193 Page 1 of 1