



Diversey Europe BV

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The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 05.05.2016

Product Name	CLEARKLENS TEGO 2001SS VH24S
Product Code	7513403
Batch Number	FMP 16077 40027
Production Date	17/03/2016
Expiration Date	EXP 17/01/2017

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	8.0	9.0	8.6
Specific Gravity (20°C)	JDM004	0.980	1.020	0.999

On behalf of Diversey site Quality Manager	Name :	Parkyisha, J. Staan
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513403	Version : 04	Date of issuing : April 19 th 2012
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 29-Apr-2016

UK32S11594583-1-1

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:	1002758
Customer Reference Number:	P026271
Product Description:	TEGO 2001 SS 25-45kGy
Validation Reference:	4.1903
Quantity Received:	132
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	128 X BATCH NO: FMP16077 40027 + 4 SAMPLES THURS 31ST MAR 2016 3 PLTS LOT 1
Other Process Details:	Dose augmentation performed at Synergy Elgin (UK31S11604102-1-1) on 15 Apr 2016 following Initial underdose (NC ref 19467). Initial Dose: min 24.5kGy and max 39.2kGy Augmentation dose received (UK31S11604102-1-1): Min 1.8kGy and Max 3.3kGy Total certifiable minimum dose: 26.3kGy Total certifiable maximum dose: 42.5kGy

Irradiation Data

Date and Time of Irradiation:	03-Apr-2016 09:00
Reference Dose Range kGy:	34.6 - 37.5
Calculated Minimum Dose kGy:	24.5

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



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Calculated Maximum Dose kGy:	39.2
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Irradiation Release Authorised By Synergy Health plc

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Wickham Laboratories

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LA1 4XS

Date Received: 06 May 2016
Date Tested: 11 May 2016
Date Test Completed: 25 May 2016
Purchase Order: PO26512

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0028808/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 06/05/2016
Test Article: TEGO 2001ss
Sample Code: FMP16077 40027
Batch Ref: 526802
Qty Received: 20 x 900mL Bottles (+ 1 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 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM09

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: 26 May 2016 16:07:56

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology