Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427



CERTIFICATE OF ANALYSIS

Date: 8/7/15

Product Name	ne CLEARKLENS TEGO 2000SS VH25S	
Product Code	7516428	
Batch Number	THP15139 38161	
Production Date	19/05/2015	
Expiration Date	19/11/2016	

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		clear Slightly,
		Liq	uid	Yellow Liquid
pH 100% (20°C)	JDM001	6.2	8.2	7.4
Specific Gravity (20°C)	JDM004	0.990	1.010	0.994

On behalf of Diversey site Quality Manager	Name:	Partylida, Mabue
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA VH25S	Version: 05	Date of issuing: June 11th 2013	



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 06-Jul-2015

UK32S11419312-2-1

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

	au illulitation	
Account Number:	100432	
Synergy Health Sales Part Reference:	1002758	
Customer Reference Number:	P024463	
Product Description:	TEGO 2001 SS 25-45kGy	
Validation Reference:	4.1903	
Quantity Received:	26	
Customer Minimum Specification kGy:	25.0	
Customer Maximum Specification kGy:	45.0	
Customer Unit Lot/Batch Number:	TEGO 2000SS, 22 X B/N FMP 15139 38161 + 4 SAMPLES THURS 04 JUN 2015 TOTAL 2 PLTS LOT 1	
- Ir	radiation Data	
Date and Time of Irradiation:	and Time of Irradiation: 04-Jul-2015 03:15	
Reference Dose Range kGy:	35.8 - 36.6	
Calculated Minimum Dose kGy:	25.3	
Calculated Maximum Dose kGy:	38.3	

CERTIFICATE OF CONFORMANCE

TO: Page: 1

Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

DATE :23/07/15
DESPATCH NO :DN34734
FMP ORDER NUMBER :SO26726

CUSTOMER REFERENCE :4701667623/7516428

LINE PART NUMBER CUSTOMER REFERENCE QUANTITY UNIT LOT REF LOT LINE

1 DEV001787 7516428

22 EA WO38161

CLEARKLENS TEGO 2000SS 900ML - BLOCK 2

BATCH NO: FMP

Labelled with UN LQ

ENVIROWASTE - 6 UNT CASE - 568.5G - PLASTIC

CERTIFICATE OF CONFORMANCE

These goods have been manufactured in accordance with FMP Quality Systems (ISO9001:2008, ISO13485:2003, ISO14001:2004) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: £ Cause.

DATE: 24 07.15



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 LA14XS

Date Received:

09 Jul 2015

Date Tested:

16 Jul 2015

Date Test Completed:

30 Jul 2015

Purchase Order:

PO24687

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0023557/3

Test Required:

Membrane Filtration by Steritest

Date Received:

09/07/2015

Test Article:

TEGO 2000ss

Sample Code:

Batch Ref: Qty Received: FMP15139 38161 20 x 900mL Bottles

Method Item Result Sterility Test by Membrane Filtration

(Steritest) Method Growth in Tryptone Soya Broth at 20-

25°C after 14 days

Growth in Fluid Thioglycollate Medium

at 30-35°C after 14 days

Volume Tested Product Standard Data Sheet MM107/01

MM107/00

MM107/02

MM107/05 FG047/psd No growth in two broths

Pass

No growth in two broths

20 x 50 mL **FM08**

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

Date: 31 Jul 2015 13:18:24

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0023557 Print Number: P0028700 Page 1 of 1

