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CERTIFICATE OF ANALYSIS

Date: 06 May 2020

| | | | |
|-----------------|-----------------------------|-------|--|
| Product Name | CLEARKLENS TEGO 2000SC VH25 | | |
| Product Code | 100868202 | | |
| Batch Number | FMP20112 | 49580 | |
| Production Date | 21/04/2020 | | |
| Expiration Date | EXP 21/04/2023 | | |

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 |
| Specific Gravity (20°C) | DM004 | 0.993 | 1.003 | 0.998 |
| pH (neat solution) | DM001 | 7.5 | 8.5 | 7.8 |
| | | | | |

| | | |
|--|----------|--------------------------------------|
| On behalf of Diversey site Quality Manger | Name: | urszula Haraburda Angelika Partynska |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10245A

| <u>Product Code</u> | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|--------------------------|-----------------|------------|
| TEGO 2000SC DV4724 | WO49580 INC 1 SAMPLE BOX | 91 | Case |
| Validation Reference Number: 4724 | | | |

Processing Run Start Date: 03-May-20 04:18 AM

Processing Run End Date: 03-May-20 11:46 AM

| | | | |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 45.0 | Calculated Min Dose (kGy): | 30.1 |
| Reference Dose Range (kGy): | 29.4- 40.5 | Calculated Max Dose (kGy): | 40.8 |

PO Number: 35340

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Tego 2000SC

Sample Description: Sample Code: Fmp20112 49580

Lucideon Sample Number: UK201974-14740

Lucideon Report Number: UK201974-14740/MFEP **Issue Number:** 1

Date Logged: 07-May-2020 **Order Number:** PO 35412

Date Reported: 03-Jun-2020 **Date(s) of Test(s):** 16-May-2020 to 03-Jun-2020

Sterility Testing

Membrane Filtration EP


Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report


03 JUN 20

Mrs Andrea Saunders

Business Support Assistant

Page 1 of 1

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