

## STERIS: Gamma Certificate Of Processing

Prepared for: ECP SAS (11507)

Gamma Process Run ID 2023-5980A

### Product Code

224513P - BIDONS 30 ML CLEARKLENS  
PLUS

### Lot Number

N/A

### Quantity UOM

4 Pallet

Validation Reference Number: S12205481

Processing Run Start Date: 19-Jan-2023 7:51 PM

Processing Run End Date: 20-Jan-2023 3:36 AM

**Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.2**

**Reference Dose Range (kGy): 26.2 - 33.1 Calculated Max Dose (kGy): 37.6**

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: CF230029 - 10/01/2023

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Signature Manifest

Reviewed and E-Signed By: **Sandrine Defazio** (Quality & production assistant)

Date/Time E-Signed: 23-Jan-2023 9:50 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QRS, EN ISO 13485 current certified version and is in alignment with EN ISO 11137-1 current certified version.

### Processing Location

Synergy Health Marseille SAS,  
a STERIS Company  
MIN 712 Les Arnavaux  
13323 Marseille Cedex 14  
France  
Phone: +33 (0) 491-214-214

*DIVERSEY*

*Clearkleans Plus*

*Sku 7515165*

*Batch nb = ENT55768 23 0025 -*

*A. VANDEVENTER - le 07/03/2023*



|                                                                                                                                                                                                 |                        |                                                    |                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------|-----------------------------------|
| <b>Customer</b><br>DIVERSEY Europe Operations BV                                                                                                                                                |                        | Management Quality Manual n° MMQ0000 (contractual) |                                   |
| <b>Product:</b><br>Clearklens plus SKU 7515165                                                                                                                                                  |                        | <b>Control report n°:</b><br>CERT 230016           |                                   |
| <b>Specification reference:</b><br>CDC Edition n°3 October 2018                                                                                                                                 |                        | <b>Purchase order n°:</b><br>4702959816            |                                   |
| <b>Analyst:</b><br>CMS                                                                                                                                                                          |                        | <b>Date of receipt:</b><br>01/09/2023              |                                   |
| <b>PHYSICAL AND CHEMICAL PROPERTIES CONTROL</b>                                                                                                                                                 |                        |                                                    |                                   |
| <b>Customer's batch n°:</b><br>ENT55768 23 002                                                                                                                                                  |                        | <b>Certificate N° STERIS:</b><br>NA                |                                   |
| <b>Date of manufacturing:</b><br>January-23                                                                                                                                                     |                        | <b>Quantity produced:</b><br>6400 x 0,03L          |                                   |
| <b>Expiry date:</b><br>January-25                                                                                                                                                               |                        | <b>FIDT N°:</b><br>1892 P                          |                                   |
| <b>ECP's batch N°:</b><br>55768                                                                                                                                                                 |                        | <b>Concentrate batch N°:</b><br>0000754964         |                                   |
| <p>The below data (limits and results) are extracted from the Certificate of Analysis written by Noemi Cazzamali (GMP Specialist) on 11/17/2021. This document was received the 01/12/2022.</p> |                        |                                                    |                                   |
| <b>Results :</b>                                                                                                                                                                                |                        |                                                    |                                   |
| <b>Characteristics analysed</b>                                                                                                                                                                 | <b>Analysis method</b> | <b>Results</b>                                     | <b>Specification</b>              |
| Appearance at 20°C                                                                                                                                                                              | PAG 183 G18 (001)      | Clear colourless to yellow liquid                  | Clear colourless to yellow liquid |
| Odour                                                                                                                                                                                           | PAG 186 G46 (001)      | As standard                                        | As standard                       |
| Specific gravity (20°C)                                                                                                                                                                         | DM-004                 | 1,035                                              | 1,010 - 1,050                     |
| pH NEAT                                                                                                                                                                                         | DM-001                 | 5,90                                               | 5,00 - 6,00                       |
| pH 1% solution                                                                                                                                                                                  | DM-001                 | 6,20                                               | 5,40 - 6,40                       |
| Viscosity (25°C, MVII, speed 21) [mPas]                                                                                                                                                         | DM-006                 | 270                                                | 250 - 350                         |
| Percent Anionic (M=350g/mol)                                                                                                                                                                    | DM-021                 | 15,69                                              | 15,50 - 16,50                     |
| Bacterial Count (CFU/ml)                                                                                                                                                                        | DM-019                 | <300                                               | <300                              |
| Batch released by A. VANDEVENTER - le 01/03/2023                                                                                                                                                |                        |                                                    |                                   |

|        |            |              |                |              |                |
|--------|------------|--------------|----------------|--------------|----------------|
| Date : | 01/09/2023 | Written by : | C. MOISSONNIER | Checked by : | A. VANDEVENTER |
|--------|------------|--------------|----------------|--------------|----------------|

LF 230249.  
reçu le 24/02/23

ENR75-LEB-002 B



Rapport N° : 23/OI/STE/041

Demandeur : ECP  
Enquirer : 395, rue Louis Lépine  
34000 MONTPELLIER

## Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane Test report - Membrane filtration sterility testing

selon la Pharmacopée Européenne 11<sup>e</sup> édition chapitre 2.6.1  
according to the 11th European Pharmacopoeia Edition, chapter 2.6.1

### ECHANTILLON(S)/SAMPLE(S)

#### Informations Client / Customer informations:

|                                                         |                          |                                                 |          |
|---------------------------------------------------------|--------------------------|-------------------------------------------------|----------|
| Désignation :<br>Product name                           | Cleaklens Plus           | Numéro de commande :<br>Order number            | CF230096 |
| Référence client :<br>Customer reference                | 7515165                  | POE :<br>SIP                                    | -        |
| Numéro de lot :<br>Batch number                         | ENT55768 23 002          | Matériau(x) :<br>Material                       | -        |
| Nombre d'échantillon(s) :<br>Sample quantity            | 1                        | Donnée de stérilisation :<br>Sterilisation data | -        |
| N° cahier des charges :<br>N° of conditions of contract | -                        |                                                 |          |
| Commentaire(s) :<br>Comments(s)                         | 10 bidons poeée de 0.03L |                                                 |          |

#### Informations Medical Group / Medical Group informations:

|                                     |                      |                                       |                      |
|-------------------------------------|----------------------|---------------------------------------|----------------------|
| Date de réception :<br>Receipt date | lundi 6 février 2023 | Date de réalisation :<br>Testing date | jeudi 9 février 2023 |
|-------------------------------------|----------------------|---------------------------------------|----------------------|

### PROTOCOLE/PROTOCOL

|                                                                |                   |                                                                       |                                                      |
|----------------------------------------------------------------|-------------------|-----------------------------------------------------------------------|------------------------------------------------------|
| Volume d'échantillon filtré :<br>Filtered sample volume        | 3 ml              | Volume de rinçage :<br>Rinsing volume                                 | 3 x 100 ml                                           |
| Solution neutralisante :<br>Neutralizing solution              | DNP + Thiosulfate | Volume d'immersion de la membrane :<br>Immersion volume of membranes  | 100 ml                                               |
| Nombre de milieux testés :<br>Number of Environment tested     | 2                 |                                                                       |                                                      |
| Conditions :<br>Conditions                                     |                   | Milieux de culture :<br>Environnement of culture                      | Température d'incubation :<br>Incubation temperature |
| Bactéries aérobies, levures, champignons<br>Aerobic and fungal |                   | Bouillon Trypcase Soja<br>Tryptone soy solution                       | 22,5 ± 2,5°C<br>14 jours<br>14 days                  |
| Bactéries anaérobies et aérobies<br>Anaerobic and aerobic      |                   | Bouillon Thioglycolate avec<br>Résazurine<br>Thioglycolate Resazurine | 32,5 ± 2,5°C<br>14 jours<br>14 days                  |
| Validation de la méthode<br>Method validation                  |                   |                                                                       |                                                      |
| 10/OI/VAL-STE/004a                                             |                   |                                                                       |                                                      |

### RESULTATS / RESULTS

| Examen de la croissance microbienne du milieu<br>Examination of the microbial growth in the media                             |                               |                                 |                |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------|----------------|
| Conditions / Milieux de culture<br>Conditions / Media of culture                                                              | Après 7 jours<br>After 7 days | Après 14 jours<br>After 14 days |                |
| Bactéries aérobies, levures et moisissures /<br>Bouillon Trypcase Soja<br>Aerobic and fungal / Tryptone soy solution          | 1<br>Limpide/Limpid           | 1<br>Limpide/Limpid             | Limpide/Limpid |
| Bactéries anaérobies et aérobies / Bouillon<br>Thioglycolate<br>Anaerobic and aerobic / Thioglycolate<br>Resazurine solution) | 0<br>Trouble/Cloudy           | 0<br>Trouble/Cloudy             | Trouble/Cloudy |
|                                                                                                                               | 1<br>Limpide/Limpid           | 1<br>Limpide/Limpid             | Limpide/Limpid |
|                                                                                                                               | 0<br>Trouble/Cloudy           | 0<br>Trouble/Cloudy             | Trouble/Cloudy |

### CONTRÔLES / CONTROLS

|                                                                                                             |   |   |
|-------------------------------------------------------------------------------------------------------------|---|---|
| Contrôle plan de travail : avant<br>/ après (UFC)<br>Work plan control: before / after<br>(CFU)             | 0 | 0 |
| Air sous flux laminaire<br>statique / dynamique (UFC)<br>Laminar flow air control: static /<br>dynamic(CFU) | 0 | 0 |

|                                                                                            |          |   |
|--------------------------------------------------------------------------------------------|----------|---|
| Contrôle de gants gauche /<br>droit (UFC) :<br>Glove control product left / right<br>(CFU) | 0        | 0 |
| Contrôle témoins de<br>manipulation :<br>Control handling indicators                       | Conforme |   |

### CONCLUSION

Les échantillons testés ne présentent pas de croissance microbienne après 14 jours d'incubation  
Tested products doesn't shown any microbial development after 14 days of incubation.

Aucun produit ne s'est révélé positif lors de cet essai.

No Product was positive during the test.

|                                                                                                                                                                                                                                                                                                |                                                       |                               |                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------|-------------------------------------------------------|
| Rédigé par :<br>Written by                                                                                                                                                                                                                                                                     | Gloria PEISEY                                         | Approuvé par :<br>Approved by | Mathilde DJAALAB                                      |
|                                                                                                                                                                                                                                                                                                | Technicienne Microbiologie<br>Microbiology Technician |                               | Technicienne Microbiologie<br>Microbiology Technician |
| Date :                                                                                                                                                                                                                                                                                         | jeudi 23 février 2023                                 |                               |                                                       |
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MedicalGroup

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