



10150632

<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 16-Feb-2022

FR01S12645987-1-1

This is to certify that Synergy Health Marseille, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 Quality System - Medical Devices

ECP SAS  
Le Millénaire  
395 rue Louis Lépine  
34000 MONTPELLIER  
FRANCE

DIVERSEY  
Clearklens plus SKU 7515165  
Batch n° : ENUT52702 22027  
A. VANDEVENTER - 08103/22 *[Signature]*

### Order Information

|                                      |                                        |
|--------------------------------------|----------------------------------------|
| Account Number:                      | 101999                                 |
| Synergy Health Sales Part Reference: | 1023394                                |
| Customer Reference Number:           | CF220208 - 08/02/2022                  |
| Product Description:                 | 224513P - BIDONS 30 ML CLEARKLENS PLUS |
| Validation Reference:                | S12205481                              |
| Quantity Received:                   | 4                                      |
| Customer Minimum Specification kGy:  | 25.0                                   |
| Customer Maximum Specification kGy:  | 40.0                                   |

### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 16-FEB-2022 02:05 |
| Calculated Minimum Dose kGy:  | 27.8              |
| Calculated Maximum Dose kGy:  | 36.0              |

Irradiation Release Authorised By Synergy Health Marseille SAS, a STERIS Company

Processing Site: M.I.N. 712 - Arnavaux, , Marseille Cedex 14, 13323 Phone No: +33 (0) 4 91 214 214

Registered Office: M.I.N. 712 - Arnavaux, 13323 Marseille Cedex 14, FRANCE

N° TVA: FR59 343 092 540

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|                                                  |                                                    |
|--------------------------------------------------|----------------------------------------------------|
| <b>Customer</b><br>DIVERSEY Europe Operations BV | Management Quality Manual n° MMQ0000 (contractual) |
|--------------------------------------------------|----------------------------------------------------|

|                                                               |                                       |
|---------------------------------------------------------------|---------------------------------------|
| <b>Product :</b> Clearklens plus SKU 7515165                  | <b>Control report n°:</b> CERT 220065 |
| <b>Specification reference :</b> CDC Edition n°3 October 2018 |                                       |
| <b>Analyst :</b> JAR                                          | <b>Purchase order n°:</b> 4702800849  |
|                                                               | <b>Date of receipt :</b> 01/31/2022   |

**PHYSICAL AND CHEMICAL PROPERTIES CONTROL**

|                                            |                                          |
|--------------------------------------------|------------------------------------------|
| <b>Customer's batch n°</b> ENT52702 22 027 | <b>Certificate N° STERIS :</b> NA        |
| <b>Date of manufacturing :</b> January-22  | <b>Quantity produced :</b> 6400 x 0,03L  |
| <b>Expiry date :</b> January-24            | <b>FIDT N° :</b> 1814 AF                 |
| <b>ECP's batch N°:</b> 52702               | <b>Concentrate batch N° :</b> 0000725209 |

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.

**Results :**

| Characteristics analysed                | Analysis method   | Results                           | Specification                     |
|-----------------------------------------|-------------------|-----------------------------------|-----------------------------------|
| 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            | 5,40                              | 5,00 - 6,00                       |
| pH 1% solution                          | DM-001            | 5,50                              | 5,40 - 6,40                       |
| Viscosity (25°C, MVII, speed 21) [mPas] | DM-006            | 261                               | 250 - 350                         |
| Percent Anionic (M=350g/mol)            | DM-021            | 16,49                             | 15,50 - 16,50                     |
| Bacterial Count (CFU/ml)                | DM-019            | <300                              | <300                              |

C : Conform NC : Not Conform  
NA : Not Applicable

Batch released by A. VANDEVENTER - 08/03/22

|                   |                         |                             |
|-------------------|-------------------------|-----------------------------|
| Date : 01/31/2022 | Written by : J. ARNOULD | Checked by : A. VANDEVENTER |
|-------------------|-------------------------|-----------------------------|





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

selon la Pharmacopée Européenne 10<sup>e</sup> édition chapitre 2.6.1  
according to the 10th European Pharmacopoeia Edition, chapter 2.6.1

**ECHANTILLON(S)/SAMPLE(S)**

**Informations Client / Customer informations:**

|                                                           |                           |                                                   |          |
|-----------------------------------------------------------|---------------------------|---------------------------------------------------|----------|
| Désignation :<br>Product name :                           | Clearklenz Plus           | Numéro de commande :<br>Order number :            | CF220266 |
| Référence client :<br>Customer reference :                | 7515165                   | POE :<br>SIP :                                    | -        |
| Numéro de lot :<br>Batch number :                         | ENT52702 22 027           | Matériau(x) :<br>Material :                       | -        |
| Nombre d'échantillon(s) :<br>Sample quantity :            | 1                         | Donnée de stérilisation :<br>Sterilization date : | -        |
| N° cahier des charges :<br>N° of conditions of contract : | -                         |                                                   |          |
| Commentaire(s) :<br>Comment(s) :                          | 10 bidons de 0,03L poolés |                                                   |          |

**Informations Medical Group / Medical Group informations:**

|                                       |                       |                                         |                       |
|---------------------------------------|-----------------------|-----------------------------------------|-----------------------|
| Date de réception :<br>Receipt date : | lundi 21 février 2022 | Date de réalisation :<br>Testing date : | mardi 22 février 2022 |
|---------------------------------------|-----------------------|-----------------------------------------|-----------------------|

**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 | Durée d'incubation<br>Incubation period                                |         |    |
| Bactéries aérobies, levures, champignons<br>Aerobic and fungal | Bouillon Trypcase Soja<br>Tryptone soy solution                       | 22,5 ± 2,5°C                                       | 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                                       | 14 jours<br>14 days                                                    |         |    |
| Validation de la méthode<br>Method validation                  |                                                                       |                                                    |                                                                        |         |    |
| 10/OI/VAL.STE/004a                                             |                                                                       |                                                    |                                                                        |         |    |

**RESULTATS / RESULTS**

| Conditions / Milieux de culture<br>Conditions / Media of culture                                                              | Examen de la croissance microbienne du milieu<br>Examination of the microbial growth in the media |                |                                 |                |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------------|---------------------------------|----------------|
|                                                                                                                               | 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                                                                                                 | Limpide/Limpid | 1                               | Limpide/Limpid |
|                                                                                                                               | 0                                                                                                 | Trouble/Cloudy | 0                               | Trouble/Cloudy |
| Bactéries anaérobies et aérobies / Bouillon<br>Thioglycolate<br>Anaerobic and aerobic / Thioglycolate<br>Resazurine solution) | 1                                                                                                 | Limpide/Limpid | 1                               | Limpide/Limpid |
|                                                                                                                               | 0                                                                                                 | Trouble/Cloudy | 0                               | Trouble/Cloudy |

**CONTRÔLES / CONTROLS**

|                                                                                                              |   |   |                                                                                            |          |   |
|--------------------------------------------------------------------------------------------------------------|---|---|--------------------------------------------------------------------------------------------|----------|---|
| Contrôle plan de travail : avant<br>/ après (UFC)<br>Work plan control: before / after<br>(CFU)              | 0 | 0 | Contrôle de gants gauche /<br>droit (UFC) :<br>Glove control product left / right<br>(CFU) | 0        | 0 |
| Air sous flux laminaire<br>statique / dynamique (UFC)<br>Laminar flow air control: static /<br>dynamic (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 : **Mathilde DUAALAB**  
Written by :

Technicienne Microbiologie  
Microbiology Technician

Approuvé par : **Marie KALIS**  
Approved by :

Responsable Laboratoire Microbiologie  
Microbiology Laboratory Manager

Date : **mardi 8 mars 2022**

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