

8943129

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

## Certificate of Irradiation

Date Issued: 03-Aug-2020

FR01S12464708-1-1

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  
ClearLens Plus SKU 7515165  
Batch n°: ENT 46828 20 183  
ML. AUGUSTE  
14/09/2020 *Auguste*

### Order Information

|                                      |                                        |
|--------------------------------------|----------------------------------------|
| Account Number:                      | 101999                                 |
| Synergy Health Sales Part Reference: | 1023394                                |
| Customer Reference Number:           | CF201059 - 27/07/2020                  |
| Product Description:                 | 224513P - BIDONS 30 ML CLEARLENDS 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: | 01-AUG-2020 02:17 |
| Calculated Minimum Dose kGy:  | 26.9              |
| Calculated Maximum Dose kGy:  | 37.0              |

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 20564 |
| <b>Specification reference :</b> CDC Edition n°3 October 2018 |                                      |
| <b>Analyst :</b> JAR                                          | <b>Purchase order n°:</b> 4702556122 |
|                                                               | <b>Date of receipt :</b> 07/20/2020  |

**PHYSICAL AND CHEMICAL PROPERTIES CONTROL**

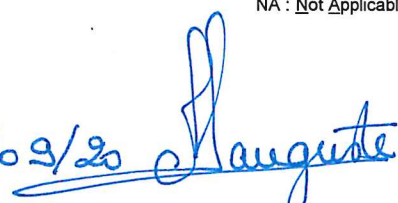
|                                            |                                         |
|--------------------------------------------|-----------------------------------------|
| <b>Customer's batch n°</b> ENT46828 20 183 | <b>Certificate N° STERIS :</b> NA       |
| <b>Date of manufacturing :</b> juil.-20    | <b>Quantity produced :</b> 6400 x 0,03L |
| <b>Expiry date :</b> July-22               | <b>FIDT N°:</b> 1892 P                  |
| <b>ECP's batch N°:</b> 46828               | <b>Concentrate batch N°:</b> 0000670929 |

The below data (limits and results) are extracted from the Certificate of Analysis written by Noemi Cazzamali (GMP Specialist) on 02/21/2020. This document was received the 03/30/2020.

**Results :**

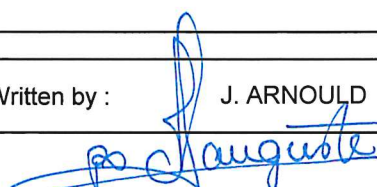
| Characteristics analysed                | Analysis method   | Results                           | Specification                     |
|-----------------------------------------|-------------------|-----------------------------------|-----------------------------------|
| Appearance at 20°C                      | 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            | 1,037                             | 1,010 - 1,050                     |
| pH NEAT                                 | DM-001            | 5,70                              | 5,00 - 6,00                       |
| pH 1% solution                          | DM-001            | 6,40                              | 5,40 - 6,40                       |
| Viscosity (25°C, MVII, speed 21) [mPas] | DM-006            | 342                               | 250 - 350                         |
| Percent Anionic (M=350g/mol)            | DM-021            | 16,45                             | 15,50 - 16,50                     |
| Bacterial Count (CFU/ml)                | DM-019            | <300                              | <300                              |

C : Conform NC : Not Conform  
NA : Not Applicable

Batch released by M. AUGUSTE 14/09/20 



|                   |                         |                         |
|-------------------|-------------------------|-------------------------|
| Date : 07/20/2020 | Written by : J. ARNOULD | Checked by : M. FERRAND |
|-------------------|-------------------------|-------------------------|






 Rapport N° : **20/OI/STE/182**  
 Report N° :

 Demandeur : **ECP**  
 Enquêter : 395, rue Louis Léprie  
 34000 MONTPELLIER

**ECP** Reçu le

**10 SEP. 2020**
**Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane**  
**Test report - Membrane filtration sterility testing**

 N° **LF201596**..... 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)**

|                                                |                       |                                                   |                          |
|------------------------------------------------|-----------------------|---------------------------------------------------|--------------------------|
| Désignation :<br>Product name :                | Clarklens Plus        | Numéro de commande :<br>Order number :            | CF201082                 |
| Référence client :<br>Customer reference :     | 7515165               | POE :<br>SIP :                                    | NA                       |
| Numéro de lot :<br>Batch number :              | ENT 46828 20 183      | Matériau(x) :<br>Material :                       | -                        |
| Date de réception :<br>Receipt date :          | vendredi 14 août 2020 | Donnée de stérilisation :<br>Sterilization data : | -                        |
| Date de réalisation :<br>Testing date :        | mercredi 26 août 2020 | Commentaire(s) :<br>Comment(s) :                  | 10 bidons de 0,3L poolés |
| Nombre d'échantillon(s) :<br>Sample quantity : | 1                     |                                                   |                          |

**PROTOCOLE/PROTOCOL**

|                                                              |                                                                        |                                         |
|--------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------|
| Volume d'échantillon :<br>Sample volume :                    | <b>3</b> ml                                                            | 3 rinçages de 100 ml de DNP Thio        |
| Solution neutralisante :<br>Neutralizing solution :          | DNP + Thiosulfate                                                      | Volume de rinçage :<br>Rinsing volume : |
| Nombre de milieux testés :<br>Number of Environment tested : | <b>2</b>                                                               | <b>3 x 100</b> ml                       |
|                                                              | Volume d'immersion de la membrane :<br>Immersion volume of membranes : | <b>100</b> ml                           |

| 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  
 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                         | 0                                                                                                 | Positifs<br>Positive | 0                               | Positifs<br>Positive |
|                                                                                                                                              | 1                                                                                                 | Négatifs<br>Negative | 1                               | Négatifs<br>Negative |
| Bactéries anaérobies et aérobies / Bouillon<br>Thioglycolate avec Résazurine<br>Anaerobic and aerobic / Thioglycolate<br>Resazurine solution | 0                                                                                                 | Positifs<br>Positive | 0                               | Positifs<br>Positive |
|                                                                                                                                              | 1                                                                                                 | Négatifs<br>Negative | 1                               | Négatifs<br>Negative |

**CONTRÔLES / CONTROLS**

|                                                                 | Avant (Before) | Après (After) |                                                           |          |
|-----------------------------------------------------------------|----------------|---------------|-----------------------------------------------------------|----------|
| Contrôle plan de travail (UFC)<br>Work plan control (CFU)       | 0              | 0             | Contrôle de gant (UFC) :<br>Glove control (CFU) :         | 0        |
| Air sous flux laminaire (UFC)<br>Laminar flow air control (CFU) |                | 0             | Contrôle stérilité milieux :<br>Media sterility control : | 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 DJAALAB**  
 Written by :

 Technicienne Biologiste  
 Biologist technician

 Approuvé par : **Christine PARET**  
 Approved by :

 Directrice Qualité  
 Quality Manager

 Date : **mercredi 9 septembre 2020**

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