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

## Certificate of Irradiation

Date Issued: 13-Jan-2021

FR01S12524393-1-1

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°: ENT51257 21 237  
ML. AUGUSTE  
18/10/2021  
*Auguste*

### Order Information

|                                      |                                        |
|--------------------------------------|----------------------------------------|
| Account Number:                      | 101999                                 |
| Synergy Health Sales Part Reference: | 1023394                                |
| Customer Reference Number:           | CF210008 - 04/01/2021                  |
| 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: | 13-JAN-2021 05:16 |
| Calculated Minimum Dose kGy:  | 28.1              |
| Calculated Maximum Dose kGy:  | 36.9              |

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

Page 1 of 1

|                                                  |                                                    |
|--------------------------------------------------|----------------------------------------------------|
| <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 210691 |
| <b>Specification reference :</b> CDC Edition n°3 October 2018 |                                       |
| <b>Analyst :</b> JAR                                          | <b>Purchase order n°:</b> 4702738153  |
|                                                               | <b>Date of receipt :</b> 08/27/2021   |

## PHYSICAL AND CHEMICAL PROPERTIES CONTROL

|                                            |                                         |
|--------------------------------------------|-----------------------------------------|
| <b>Customer's batch n°</b> ENT51257 21 237 | <b>Certificate N° STERIS :</b> NA       |
| <b>Date of manufacturing :</b> August-21   | <b>Quantity produced :</b> 6400 x 0,03L |
| <b>Expiry date :</b> August-23             | <b>FIDT N°:</b> 1892 P                  |
| <b>ECP's batch N°:</b> 51257               | <b>Concentrate batch N°:</b> 0000686037 |

The below data (limits and results) are extracted from the Certificate of Analysis written by Noemi Gazzamali (GMP Specialist) on 08/28/2020. This document was received the 12/14/2020.

### 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            | 1,038                             | 1,010 - 1,050                     |
| pH NEAT                                 | DM-001            | 5,90                              | 5,00 - 6,00                       |
| pH 1% solution                          | DM-001            | 6,30                              | 5,40 - 6,40                       |
| Viscosity (25°C, MVII, speed 21) [mPas] | DM-006            | 290                               | 250 - 350                         |
| Percent Anionic (M=350g/mol)            | DM-021            | 16,11                             | 15,50 - 16,50                     |
| Bacterial Count (CFU/ml)                | DM-019            | <300 CFU/ml                       | <300                              |

C : Conform NC : Not Conform  
NA : Not Applicable

Batch released by ML. AUGUSTE 18/10/2021

*Auguste*

|                   |                         |                          |
|-------------------|-------------------------|--------------------------|
| Date : 08/30/2021 | Written by : J. ARNOULD | Checked by : ML. AUGUSTE |
|-------------------|-------------------------|--------------------------|

*Auguste*

*Auguste*

*Auguste*  
14 OCT 2021  
N° LF 212 069

|                                                                                                                                                                                                                                                                                                                      |                                                                                        |                                                                                     |                                                                                                        |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------|
| <br><b>MedicalGroup</b><br><small>Implant Coating Experts</small>                                                                                                                                                                                                                                                    |                                                                                        | Rapport N° : <b>21/OI/STE/122</b><br>Report N° :                                    |                                                                                                        |                |
|                                                                                                                                                                                                                                                                                                                      |                                                                                        | Demandeur : <b>ECP</b><br>Enquêter : 395, rue Louis Lépine<br>34000 MONTPELLIER     |                                                                                                        |                |
| <b>Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane</b><br><b>Test report - Membrane filtration sterility testing</b>                                                                                                                                                                  |                                                                                        |                                                                                     |                                                                                                        |                |
| selon la Pharmacopée Européenne 10 <sup>e</sup> édition chapitre 2.6.1<br>according to the 10th European Pharmacopoeia Edition, chapter 2.6.1                                                                                                                                                                        |                                                                                        |                                                                                     |                                                                                                        |                |
| <b>ECHANTILLON(S)/SAMPLE(S)</b>                                                                                                                                                                                                                                                                                      |                                                                                        |                                                                                     |                                                                                                        |                |
| <b>Informations Client / Customer informations:</b>                                                                                                                                                                                                                                                                  |                                                                                        |                                                                                     |                                                                                                        |                |
| Désignation :<br><small>Product name</small>                                                                                                                                                                                                                                                                         | Clarklens Plus                                                                         | Numéro de commande :<br><small>Order number</small>                                 | CF211295                                                                                               |                |
| Référence client :<br><small>Customer reference</small>                                                                                                                                                                                                                                                              | 7515165                                                                                | POE :<br><small>SiP</small>                                                         | -                                                                                                      |                |
| Numéro de lot :<br><small>Batch number</small>                                                                                                                                                                                                                                                                       | ENT51257 21 237                                                                        | Matériau(x) :<br><small>Material</small>                                            | -                                                                                                      |                |
| Nombre d'échantillon(s) :<br><small>Sample quantity</small>                                                                                                                                                                                                                                                          | 1                                                                                      | Donnée de stérilisation :<br><small>Sterilization data</small>                      | -                                                                                                      |                |
| N° cahier des charges :<br><small>N° of conditions of contract</small>                                                                                                                                                                                                                                               | -                                                                                      |                                                                                     |                                                                                                        |                |
| Commentaire(s) :<br><small>Comment(s)</small>                                                                                                                                                                                                                                                                        |                                                                                        | 10 bidons poolés de 30 mL                                                           |                                                                                                        |                |
| <b>Informations Medical Group / Medical Group informations:</b>                                                                                                                                                                                                                                                      |                                                                                        |                                                                                     |                                                                                                        |                |
| Date de réception :<br><small>Receipt date</small>                                                                                                                                                                                                                                                                   | mardi 21 septembre 2021                                                                | Date de réalisation :<br><small>Testing date</small>                                | jeudi 30 septembre 2021                                                                                |                |
| <b>PROTOCOLE/PROTOCOL</b>                                                                                                                                                                                                                                                                                            |                                                                                        |                                                                                     |                                                                                                        |                |
| Volume d'échantillon filtré :<br><small>Filtred sample volume</small>                                                                                                                                                                                                                                                | 30 ml                                                                                  | Volume de rinçage :<br><small>Rinsing volume</small>                                | 3 x 100 ml                                                                                             |                |
| Solution neutralisante :<br><small>Neutralizing solution</small>                                                                                                                                                                                                                                                     | DNP + Thiosulfate                                                                      | Volume d'immersion de la membrane :<br><small>Immersion volume of membranes</small> | 100 ml                                                                                                 |                |
| Nombre de milieux testés :<br><small>Number of Environment tested</small>                                                                                                                                                                                                                                            | 2                                                                                      |                                                                                     |                                                                                                        |                |
| <small>Conditions</small>                                                                                                                                                                                                                                                                                            | <small>Milieux de culture</small>                                                      | <small>Température d'incubation</small>                                             | <small>Durée d'incubation</small>                                                                      |                |
| <small>Conditions</small>                                                                                                                                                                                                                                                                                            | <small>Environnement of culture</small>                                                | <small>Incubation temperature</small>                                               | <small>Incubation period</small>                                                                       |                |
| Bactéries aérobies, levures, champignons<br><small>Aerobic and fungal</small>                                                                                                                                                                                                                                        | Bouillon Trypcase Soja<br><small>Tryptone soy solution</small>                         | 22,5 ± 2,5°C                                                                        | 14 jours<br>14 days                                                                                    |                |
| Bactéries anaérobies et aérobies<br><small>Anaerobic and aerobic</small>                                                                                                                                                                                                                                             | Bouillon Thioglycolate avec<br>Résazurine<br><small>Thioglycolate Resazurine</small>   | 32,5 ± 2,5°C                                                                        | 14 jours<br>14 days                                                                                    |                |
| Validation de la méthode<br><small>Method validation</small> 10/OI/VAL.STE/004a                                                                                                                                                                                                                                      |                                                                                        |                                                                                     |                                                                                                        |                |
| <b>RESULTATS / RESULTS</b>                                                                                                                                                                                                                                                                                           |                                                                                        |                                                                                     |                                                                                                        |                |
| Examen de la croissance microbienne du milieu<br><small>Examination of the microbial growth in the media</small>                                                                                                                                                                                                     |                                                                                        |                                                                                     |                                                                                                        |                |
| <small>Conditions / Milieux de culture</small>                                                                                                                                                                                                                                                                       | <small>Après 7 jours</small>                                                           |                                                                                     | <small>Après 14 jours</small>                                                                          |                |
| <small>Conditions / Media of culture</small>                                                                                                                                                                                                                                                                         | <small>After 7 days</small>                                                            |                                                                                     | <small>After 14 days</small>                                                                           |                |
| Bactéries aérobies, levures et moisissures /<br>Bouillon Trypcase Soja<br><small>Aerobic and fungal / Tryptone soy solution</small>                                                                                                                                                                                  | 1                                                                                      | Limpide/Limpid                                                                      | 1                                                                                                      | Limpide/Limpid |
|                                                                                                                                                                                                                                                                                                                      | 0                                                                                      | Trouble/Cloudy                                                                      | 0                                                                                                      | Trouble/Cloudy |
| Bactéries anaérobies et aérobies / Bouillon<br>Thioglycolate<br><small>Anaerobic and aerobic / Thioglycolate</small>                                                                                                                                                                                                 | 1                                                                                      | Limpide/Limpid                                                                      | 1                                                                                                      | Limpide/Limpid |
|                                                                                                                                                                                                                                                                                                                      | 0                                                                                      | Trouble/Cloudy                                                                      | 0                                                                                                      | Trouble/Cloudy |
| <b>CONTRÔLES / CONTROLS</b>                                                                                                                                                                                                                                                                                          |                                                                                        |                                                                                     |                                                                                                        |                |
| Contrôle plan de travail : avant<br>/ après (UFC)<br><small>Work plan control: before / after (CFU)</small>                                                                                                                                                                                                          | 0                                                                                      | 0                                                                                   | Contrôle de gants gauche /<br>droit (UFC) :<br><small>Glove control product left / right (CFU)</small> |                |
| Air sous flux laminaire<br>statique / dynamique (UFC)<br><small>Laminar flow air control: static / dynamic (CFU)</small>                                                                                                                                                                                             | 0                                                                                      | 0                                                                                   | 0      0                                                                                               |                |
|                                                                                                                                                                                                                                                                                                                      |                                                                                        |                                                                                     | Contrôle témoins de<br>manipulation :<br><small>Control handling indicators</small>                    |                |
|                                                                                                                                                                                                                                                                                                                      |                                                                                        |                                                                                     | Conforme                                                                                               |                |
| <b>CONCLUSION</b>                                                                                                                                                                                                                                                                                                    |                                                                                        |                                                                                     |                                                                                                        |                |
| Les échantillons testés ne présentent pas de croissance microbienne après 14 jours d'incubation<br><i>Tested products doesn't shown any microbial development after 14 days of incubation.</i><br><b>Aucun</b> produit ne s'est révélé positif lors de cet essai.<br><i>No Product was positive during the test.</i> |                                                                                        |                                                                                     |                                                                                                        |                |
| Rédigé par :<br><small>Written by</small>                                                                                                                                                                                                                                                                            | Gloria PEISEY<br><small>Technicienne Microbiologie<br/>Microbiology Technician</small> | Approuvé par :<br><small>Approved by</small>                                        | Mathilde DJAALAB<br><small>Technicienne Microbiologie<br/>Microbiology Technician</small>              |                |
| Date :                                                                                                                                                                                                                                                                                                               | jeudi 14 octobre 2021                                                                  |                                                                                     |                                                                                                        |                |
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