

5792437

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

# Certificate of Irradiation

Date Issued: 06-Sep-2017

FR01S11955735-1-1

This is to certify that Synergy Health Marseille has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products  
EN ISO 9001:2008 Quality Management System  
EN ISO 13485:2012 Quality System - Medical Devices

ECP ENTEGRIS CLEANING PROCESS  
Le Millénaire  
395 rue Louis Lépine  
34000 MONTPELLIER  
FRANCE

DIVERSEY  
Cleaklens IPA Airless v4.1 70%  
Batch n°: ENT 33795 17 215  
M.L. AUGUSTE  
18/09/2017  
*[Signature]*

## Order Information

|                                      |                                                  |
|--------------------------------------|--------------------------------------------------|
| Account Number:                      | 101999                                           |
| Synergy Health Sales Part Reference: | 1023388                                          |
| Customer Reference Number:           | CF171143 - 30/08/2017                            |
| Product Description:                 | ESSAI - ECP ENTEGRIS CLEANING PROCESS            |
| Quantity Received:                   | 1                                                |
| Customer Unit Lot/Batch Number:      | ENT33795 17 215                                  |
| Other Process Details:               | Doses prescrites par le client : 25,0 - 40,0 kGy |

## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 06-SEP-2017 07:36 |
| Calculated Minimum Dose kGy:  | 26.8              |
| Calculated Maximum Dose kGy:  | 35.0              |

Irradiation Release Authorised By Synergy Health plc

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                            |  | Management Quality Manual n° MMQ0000 (contractual) |  |
| <b>Product :</b><br><br>Clearklens IPA Airless VH1 70% |  | <b>Control report n° :</b><br>CERT 17566           |  |
| <b>Specification reference :</b><br>NA                 |  | <b>Purchase order n° :</b><br>4702070649           |  |
| <b>Analyst :</b><br>JAR                                |  | <b>Date of receipt :</b><br>09/11/2017             |  |

**PHYSICAL AND CHEMICAL PROPERTIES CONTROL**

|                                |                 |                                    |               |
|--------------------------------|-----------------|------------------------------------|---------------|
| <b>Customer's batch n° :</b>   | ENT33795 17 215 | <b>ISOTRON certificate(s) n° :</b> | S119557350101 |
| <b>Date of manufacturing :</b> | 09/2017         | <b>Produced quantity :</b>         | 312 x 0,25L   |
| <b>Expiry date :</b>           | 09/2019         | <b>FIDT N° :</b>                   | 1896 ind 0    |
| <b>ECP's batch n° :</b>        | 33795           | <b>Date of analysis :</b>          | 09/12/2017    |

**Résultats :**

| Analyzed characteristics             | Method of analysis | State in the production  | Specification            |
|--------------------------------------|--------------------|--------------------------|--------------------------|
|                                      |                    | Beginning                |                          |
| Specific gravity (base) (21°C)       | IDT0301            | 0,868                    | 0,865 - 0,875            |
| Appearance (base) 21°C               | NA                 | Clear, colourless liquid | Clear, colourless liquid |
| Microbiological contagion of the EDI | IDT0236            | 4 CFU / 100 mL           | < 10 CFU /100mL          |

C : Conform NC : Not Conform  
NA : Not Applicable

**Conclusion :** ☒ CONFORM ☐ NOT CONFORM

Batch released by M.L. AUGUSTE 18/09/2017 *M. L. Auguste*

|                   |                         |                           |
|-------------------|-------------------------|---------------------------|
| Date : 09/18/2017 | Written by : J. ARNOULD | Checked by : M.L. AUGUSTE |
|-------------------|-------------------------|---------------------------|

Copyright policy available under « EU Specific Documents » of our Web Portal:  
<http://www.criver.com/customer-service/resources/portal-logins>, section "Endosafe" Customer Web Portal".

pour le client / for customer n° : 220553

Edité par :  
Charles River  
Endotoxin and Microbial Detection  
Tél. : +33 (0)4 37 50 25 46  
Email : Endosafe.labEU@crf.com

ENTEGRIS CLEANING PROCESS / ECP  
A l'attention de Mr Olivier TASSART  
395 Rue Louis LEPINE  
34000 MONTPELLIER

## ESSAI DES ENDOTOXINES BACTERIENNES *Bacterial Endotoxins Test*

Contrat Technique  
Technical Contract

ENDO 90

Technique / Method

Méthode D  
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception  
Simple delivery date

14 September 2017

Date d'analyse  
Testing date

14 September 2017

Nbre d'échantillons  
Number of samples

1

**cofrac**  
**ESSAIS**  
ACCREDITATION  
N° 1-5805  
Scope available  
on [www.cofrac.fr](http://www.cofrac.fr)

Opérateur / Operator  
Arthur GIERCZAK  
Tech. de laboratoire / Lab. Technician

15 SEP. 2017

Produit / Product  
CLEARKLENS IPA Airless

Limite en endotoxines / Endotoxin limit (Entegris)  
0,25 UI/mL

*Les essais ont été réalisés en accord avec la Pharmacopée Européenne en vigueur, chapitre "2.6.14 – Endotoxines Bactériennes" harmonisé avec les Pharmacopées Américaine et Japonaise.*

*The assay was performed in compliance with the European Pharmacopoeia in force, chapter "2.6.14 – Bacterial endotoxins", harmonized in collaboration with the American and Japanese Pharmacopoeias.*

ID produit / product ID  
Poche Clearklens IPA 250 mL Airless

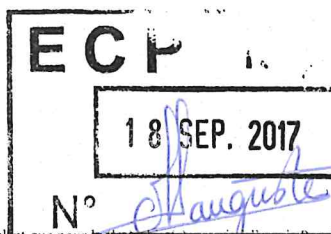
Conditions opératoires / Operational conditions  
Sauf indication contraire, les échantillons sont dilués au 1/50 dans de l'eau EEB (Eau pour les Endotoxines Bactériennes).  
*Unless otherwise specified, samples are tested at dilution 1/50 in LRW (LAL Reagent Water).*

Lot / Prélèvement / Numéro  
Batch / Sample / Number

ENT 33795 17 215

Concentration en endotoxines  
Endotoxin amount Unités  
Units

< 0,25 UI/mL



Note : les résultats ne valent que pour le (les) objet(s) soumis à l'essai. Results are valid only for (the) object(s) tested.  
D'autre part, le(s) résultat(s) ne tiennent pas compte de l'incertitude de mesure de l'essai. Moreover, results does not take into account the test uncertainty.

Approbateur Qualité / Quality Reviewer

Approbateur Technique / Technical Reviewer

Vanessa SAVOYE  
Adjointe technique laboratoire

Non Applicable cGMP

microbial solutions

9 allée Moulin Berger - 69130 Ecully - France

Tel : 00 33 437 50 25 30 • Fax : 00 33 437 50 25 34 • [www.criver.com](http://www.criver.com)

Charles River Endotoxin Microbial Detection Europe S.A.S. • Capital : 24 440 903 € • VAT No. FR 54 790 161 723 • SIREN : 790 161 723 • APE 4669C

15 SEP. 2017