

**CONTROL REPORT**

JohnsonDiversey



Diversey

|                                                       |  |                                                     |  |
|-------------------------------------------------------|--|-----------------------------------------------------|--|
| <b>Customer</b><br>DIVERSEY                           |  | Management Quality Manual n° MMMQ0000 (contractual) |  |
| <b>Product :</b><br><br>Clearklens Bi-Spore RTU VH26S |  | <b>Control report n° :</b><br>CERT 11447            |  |
| <b>Specification reference :</b><br>NA                |  | <b>Purchase order n° :</b><br>4701087482            |  |
| <b>Analyst :</b><br>LGR/GGE                           |  | <b>Date of reception :</b><br>12/07/2011            |  |

**PHYSICAL AND CHEMICAL PROPERTIES CONTROL**

|                                               |                                                          |
|-----------------------------------------------|----------------------------------------------------------|
| <b>Customer's batch n° :</b> ENT 16298 11 341 | <b>ISOTRON certificate(s) n° :</b> 17273101 and 17243301 |
| <b>Date of manufacturing :</b> 12/07/2011     | <b>Produced quantity :</b> 480 x 5L                      |
| <b>Expiry date :</b> 12/2012                  | <b>FIDT N° :</b> 1816 ind N                              |
| <b>ECP's batch n° :</b> 16298                 | <b>Date of analysis :</b> 12/07/2011                     |

**Results :**

| Solution                                        | Analyzed characteristics                | Method of analysis | State in the production | Specification           |
|-------------------------------------------------|-----------------------------------------|--------------------|-------------------------|-------------------------|
|                                                 |                                         |                    | Beginning               |                         |
| Bi-Spore Activator Solution                     | Appearance (20°C)                       | NA                 | Clear colourless liquid | Clear colourless liquid |
|                                                 | pH (20°C)                               | NA                 | 12,46                   | 11,5 - 13,5             |
|                                                 | Specific gravity (20°C)                 | IDT 0301           | 1,015                   | 1,015 - 1,035           |
| Bi-Spore Base Solution RTU                      | Appearance (20°C)                       | NA                 | Clear blue liquid       | Clear blue liquid       |
|                                                 | pH (20°C)                               | NA                 | 2,91                    | 2,5 - 4,5               |
|                                                 | Specific gravity (20°C)                 | IDT 0301           | 0,998                   | 0,990 - 1,010           |
| Bi-Spore Activator Solution + Base Solution RTU | Appearance (20°C)                       | NA                 | Clear yellow liquid     | Clear yellow liquid     |
|                                                 | pH (20°C)                               | NA                 | 3,3                     | 2,5 - 5,5               |
|                                                 | Specific gravity (20°C)                 | IDT 0301           | 1,000                   | 1,000 - 1,010           |
|                                                 | Dosage of the material chlorine dioxide | IDT 0261           | 263 ppm                 | 230 - 280 ppm           |
| Microbiological contagion of the WFI            |                                         | IDT 0236           | 8 CFU/100mL             | < 10 cfu/100mL          |

C : Conform NC : Not Conform  
NA : Not Applicable

**Conclusion :**☒ CONFORM☐ NOT CONFORM

|                   |                       |                        |
|-------------------|-----------------------|------------------------|
| Date : 12/13/2011 | Written by : L.GRESSE | Checked by : D. GHERSY |
|-------------------|-----------------------|------------------------|

IMP 0180 - L

## Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane

### Test report - Membrane filtration sterility testing

selon la Pharmacopée Européenne 7<sup>e</sup> édition chapitre 2.6.1  
according to the protocol 2.6.1 described into the seventh European Pharmacopoeia Edition

#### ECHANTILLON(S) - SAMPLES

|                                            |                     |                                               |                  |
|--------------------------------------------|---------------------|-----------------------------------------------|------------------|
| Désignation :<br>Product name              | ClearKlens Bi-spore | Numéro de commande<br>Order number            | CF 111 069       |
| Référence client :<br>Customer reference   | 7518163             | POE :<br>SIP                                  | -                |
| Numéro de lot :<br>Batch number            | ENT 16298 11 341    | Matériau(x) :<br>Material                     | -                |
| Date de réception :<br>Receipt date        | 14 décembre 2011    | Donnée de stérilisation<br>Sterilization data | -                |
| Date de réalisation :<br>Testing date      | 14 décembre 2011    | Commentaire(s)<br>Comment(s)                  | 10 bidons poolés |
| Nombre d'échantillon(s)<br>Sample quantity | 1                   |                                               |                  |

#### PROTOCOLE - PROTOCOL

| Volume d'échantillon :<br>Product tested volume                | <b>500</b>                                                                  | Volume de rinçage<br>Rinsing volume                                  | <b>3 x 100</b> ml                       |
|----------------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------|
| Solution neutralisante :<br>Neutralizing solution              | <b>DNP + Thiosulfate</b>                                                    | Volume d'immersion de la membrane :<br>Immersion volume of membranes | <b>100</b> ml                           |
| Nombre de milieux testés<br>Tested media quantity              | <b>2</b>                                                                    |                                                                      |                                         |
| Conditions<br>Conditions                                       | Milieux de culture<br>Media                                                 | 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 Résazurine<br>Thioglycolate Resazurine solution | 32,5 ± 2,5°C                                                         | 14 jours<br>14 days                     |
| Validation de la méthode<br>Method validation                  |                                                                             |                                                                      |                                         |
| <b>09/OI/VAL-STE/017</b>                                       |                                                                             |                                                                      |                                         |

#### RESULTATS - RESULTS

| Conditions / Milieux de culture<br>Conditions / Media                                                                                     | Examen de la croissance microbienne du milieu<br>Assessment of the media microbial development |                      |                                 |                      |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------------------|---------------------------------|----------------------|
|                                                                                                                                           | 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                      | -                                                                                              | Positifs<br>positive | 0                               | Positifs<br>positive |
|                                                                                                                                           | -                                                                                              | Négatifs<br>negative | 1                               | Négatifs<br>negative |
| Bactéries anaérobies et aérobies / Bouillon<br>Thioglycolate avec Résazurine<br>Anaerobic and aerobic / Thioglycolate Resazurine solution | -                                                                                              | Positifs<br>positive | 0                               | Positifs<br>positive |
|                                                                                                                                           | -                                                                                              | Négatifs<br>negative | 1                               | Négatifs<br>negative |

#### CONTRÔLES - CONTROLS

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

#### CONCLUSION - 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  
Redacted by

Technicien Biologiste

Date : mercredi 28 décembre 2011

Approuvé par  
Approved by

Directeur Général

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**MedicalLab**

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EN ISO 13485 (2003)

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# CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

**Isotron France S.A.S.**

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE



CERTIFY THAT WE TREATED BY GAMMA RADIATION ACCORDING TO THE SPECIFIC CUSTOMER'S REQUIREMENTS AND TO :

- the specification of treatment # 224503P
- The requirements of the European Pharmacopoeia
- the results of the dose mapping # 110505 of 30/03/2006

THE FOLLOWING PRODUCTS : (according to the customer's indication)

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5L BOTTLE KIT

Customer's reference : ORDER # CF110952 OF 09/11/11

Quantity : 5 PALLETS

Irradiation date : 2011.11.21

Irradiation dose : 16.8 kGy to 22.0 kGy

Irradiation batch number : 17243301

*DIVERSEY LTD*  
*Charlton Bi-Hore*  
*Batch ENT16298 n 347.*  
*le 27/12/2011*  
*PO [signature]*

The control of the applied radiation dose is done by Isotron France SAS using Red Perspex dosimeters calibrated by the English National Physical Laboratory.

**Isotron France S.A.S.,**

**H. OSMAS**

Process Control Officer

Certificate # 17243301 / 1

**S. LE GONIDEC**

Quality Assistant

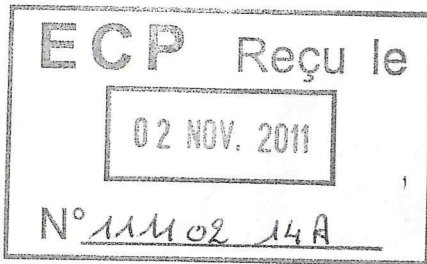
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CERTIFY THAT WE TREATED BY GAMMA RADIATION ACCORDING TO THE SPECIFIC CUSTOMER'S REQUIREMENTS AND TO :

- the specification of treatment # 224514P
- The requirements of the European Pharmacopoeia
- the results of the dosemapping # 135901 of 28/10/2008

THE FOLLOWING PRODUCTS : (according to the customer's indication)

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : BOTTLES 100 ML + STOPPERS

Customer's reference : ORDER # CF110910 OF 27/10/11

Quantity : 1 PALLET

Irradiation date : 2011.11.01

Irradiation dose : 26.4 kGy to 32.4 kGy

Irradiation batch number : 17195701

*DIVERSEY LTD*  
*Uckfield Bi-Store*  
*Batch ENT-16298 N 341*  
*le 27/11/2011*  
*PO C. Simonin*

The control of the applied radiation dose is done by Isotron France SAS using Red Perspex dosimeters calibrated by the English National Physical Laboratory.

**Isotron France S.A.S.,**

**H. OSMAS**

Process Control Officer

Certificate # 17195701 / 1

**C. SIMONIN**

Quality Officer