

# CONTROL REPORT

**Customer**

JOHNSON DIVERSEY LTD

Management Quality Manual n° MMMQ0000 (contractual)

**Product :**

Clearklens TEGO 2000 RTU VH25S

**Control report n° :**

CERT 9810

**Specification reference :** NA**Analyst :** LGR**Purchase order n° :**

4700821976

**Date of receipt :**

09/2009

## CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

**Customer's batch n° :** ENT 07728 09 244**ISOTRON certificate n° :** 14501401**Date of manufacturing :** 09/2009**Produced quantity :** 171 x 5L**Expiry date :** 09/2010**FIDT N° :** FIDT 1813 C**ECP's batch n° :** 07728**Date of analysis :** 03/09/2009**Résultats :**

| Analyzed characteristics             | Method of analysis | State in the production | Specification  |
|--------------------------------------|--------------------|-------------------------|----------------|
|                                      |                    | Beginning               |                |
| Appearance 20°C                      | NA                 | C                       | Clear liquid   |
| Specific gravity (20°C)              | IDT0301            | 0,999                   | 0,980 - 1,000  |
| pH (20°C)                            | NA                 | 7,66                    | 7,3 - 8,2      |
| Microbiological contagion of the EDI | IDT0236            | < 1 cfu/100mL           | < 10 cfu/100mL |

C : Conform NC : Not Conform  
NA : Not Applicable

**Conclusion :** ☒ CONFORM☐ NOT CONFORM

Date : 03/09/2009

Analyst : L. GRESSE

Checked : D. CHEUNG

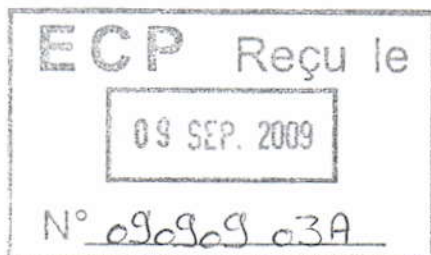
# CERTIFICATE OF TREATMENT BY GAMMA RADIATION

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 dosmapping # 110505 of 30/03/2006

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

**Customer** : ECP ENTEGRIS CLEANING PROCESS

**Product** : BIDONS 5l + BOUCHONS

**Customer's reference** : Order # CF090074 of 26/08/09

**Quantity** : 5 pallets

**Irradiation date** : 2009.08.27

**Irradiation dose** : 18.9 kGy to 26.1 kGy

**Irradiation batch number** : 14501401

*Clearkens DEGO 2000 RTU*

*lot ENT 04428 09 244*

*Date fab : 09 / 2009*

*Date per : 09 / 2010*

*J. BURGOS le 25/09/09*

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.,**

**S. LE GONIDEC**  
Quality Assistant

Certificate # 14501401 / 1

**C. SIMONIN**  
Quality Officer

Report n° : **09/OI/STE/150**

Sponsor : **ECP**  
395, rue Louis Léprie  
34000 MONTPELLIER

**Test report Essay of Sterility - Method filtration on membranes**

According to the protocol 2.6.1 described into the sixth European Pharmacopoe Edition

**TEST ARTICLE**

|                           |                   |                      |          |
|---------------------------|-------------------|----------------------|----------|
| Name of product :         | ClearKlens TEGO   | Order number :       | CF090541 |
| Customer reference :      | 7516051           | Internal reference : |          |
| Batch number :            | ENT07 728 09 244  | Material :           |          |
| Date of receipt :         | 10 septembre 2009 | Date sterilization : |          |
| Date of test :            | 10 septembre 2009 | Comment(s) :         |          |
| Quantity of used sample : | 10                |                      |          |

**PROTOCOL**

|                            |            |                                 |            |
|----------------------------|------------|---------------------------------|------------|
| Tested volume of product : | 500        | ml                              |            |
| Neutralizing solution :    | DNP + Thio | Rinsing volume :                | 3 x 100 ml |
| Number of media tested :   | 2          | Immersion volume of membranes : | 100 ml     |

| Conditions            | Media                             | Incubation temperature | Time of incubation |
|-----------------------|-----------------------------------|------------------------|--------------------|
| Aerobic and fugal     | Tryptone soy solution             | 22,5 ± 2,5°C           | 14 days            |
| Anaerobic and aerobic | Thioglycolate Résazurine solution | 32,5 ± 2,5°C           | 14 days            |

Method validation : **09/OI/VAL.STE/022**

**RESULTS**

| Conditions                        | Assessment of the media turbidimetry |          |               |          |
|-----------------------------------|--------------------------------------|----------|---------------|----------|
|                                   | After 7 days                         |          | After 14 days |          |
| Tryptone soy solution             | 0                                    | positive | 0             | positive |
|                                   | 5                                    | negative | 5             | negative |
| Thioglycolate Résazurine solution | 0                                    | positive | 0             | positive |
|                                   | 5                                    | negative | 5             | negative |

**CONTROLS**

|                                           |   |   |                           |          |
|-------------------------------------------|---|---|---------------------------|----------|
| Work plan control<br>(before and after) : | 0 | 0 | Glove control :           | Conforme |
| Air control :                             | 0 |   | Media sterility control : | Conforme |

**CONCLUSION**

The tested product doesn't shown any microbial development after 14 days of incubation.

**No** product has been positive during the test.

Redact by : **BERTHOME Audrey**  
Technicien Biologiste

Approved by : **MARTINHO Alice**  
Ingénieur Biologiste

Date : **jeudi 24 septembre 2009**

Results and conclusion apply only on the test article tested. Any extrapolation of these data to other samples is the responsibility of the Sponsor.

**MedicalLab**

Microbiological and physico-chemical analysis - process validation  
EN ISO 13485 (2003)

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**ECP** Reçu le

**24 SEP. 2009**

N° **090924 JoA**