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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 28-Feb-2017

FR01S11815892-1-1

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
clearklems Bi-Spore RTU VH26S
Batch n°: ENT 31493 17 030
M.L. AUGUSTE le 16/04/2017
M. Auguste

Order Information

Account Number:	101999
Synergy Health Sales Part Reference:	1023395
Customer Reference Number:	CF170173 - 09/02/2017
Product Description:	224514P - BOTTLES 100 ML + STOPPERS
Validation Reference:	S11215019
Quantity Received:	1
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0

Irradiation Data

Date and Time of Irradiation:	27-FEB-2017 10:04
Calculated Minimum Dose kGy:	27.6
Calculated Maximum Dose kGy:	35.5

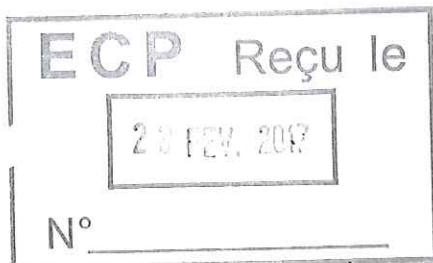
Irradiation Release Authorised By Synergy Health plc

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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 23-Feb-2017

FR01S11815895-1-1

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
ClearkPens Bi-Spore RTU VH26S
Batch n°: ENT 31493 H 030
H.L. AUGUSTE le 16/04/2017

Order Information

Account Number:	101999
Synergy Health Sales Part Reference:	1023397
Customer Reference Number:	CF170210 - 20/02/2017
Product Description:	224516P - KITS BIDONS 5L
Validation Reference:	179848
Quantity Received:	1
Customer Minimum Specification kGy:	15.0
Customer Maximum Specification kGy:	30.0

Irradiation Data

Date and Time of Irradiation:	22-FEB-2017 18:07
Calculated Minimum Dose kGy:	20.0
Calculated Maximum Dose kGy:	25.7

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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Customer DIVERSEY LTD		Management Quality Manual n° MMQ0000 (contractual)	
Product : Clearklens Bi-Spore RTU VH26S		Control report n° : CERT 17119	
Specification reference : NA		Purchase order n° : 4701991125	
Analyst : MJA		Date of reception : 03/08/2017	

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° : ENT3149317030	SYNERGY HEALTH certificate(s) n° : S118158950101
Date of manufacturing : 03/2017	Produced quantity : 160 x 5L
Expiry date : 02/2019	FIDT N° : 1816 ind AA
ECP's batch n° : 31493	Date of analysis : 03/08/2017

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	11,57	9,0 - 12,5
	Specific gravity (20°C)	IDT 0301	1,0067	1,004 - 1,020
Bi-Spore Base Solution RTU	Appearance (20°C)	NA	Clear colourless liquid	Clear colourless liquid
	pH (20°C)	NA	2,82	2,5 - 5,0
	Specific gravity (20°C)	IDT 0301	1,000	1,000 - 1,010
Bi-Spore Activator Solution + Base Solution RTU	Appearance (20°C)	NA	Clear yellow liquid	Clear yellow liquid
	pH (20°C)	NA	2,99	2,5 - 5,0
	Specific gravity (20°C)	IDT 0301	1,000	1,000 - 1,010
	Dosage of the materiel chlorine dioxide	IDT 0261	141,75	100 - 180 ppm
Microbiological contagion of the WFI		IDT 0236	8	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : ☒ CONFORM ☐ NOT CONFORM

Batch released by H.L. AUGUSTE le 16/04/2017

Date : 03/14/2017	Edited : A. PHILIPPON	Checked : L. RUBINI
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Rapport d'essai - Essai de st  rit   par la m  thode de filtration sur membrane
Test report - Membrane filtration sterility testing

selon la Pharmacop  e Europ  enne 8     dition chapitre 2.6.1
according to the 8th European Pharmacopoeia Edition, chapter 2.6.1

ECHANTILLON(S)/SAMPLE(S)

D��signation : Product name :	Clearklens Bi-Spore	Num��ro de commande : Order number :	CF170174
R��f��rence client : Customer reference :	7516197	POE : SIP :	-
Num��ro de lot : Batch number :	ENT 31493 17 030	Mat��riau(x) : Material :	-
Date de r��ception : Receipt date :	mercredi 15 mars 2017	Donn��e de st��rilisation : Sterilization data :	-
Date de r��alisation : Testing date :	mercredi 15 mars 2017	Commentaire(s) : Comment(s) :	10 bidons pool��s
Nombre d'��chantillon(s) : Sample quantity :	2		

PROTOCOLE/PROTOCOL

Volume d'��chantillon : Sample volume :	500	ml	3 rin��ages de 100 ml de DNP Thio
Solution neutralisante : Neutralizing solution :	DNP + Thiosulfate	Volume de rin��age : Rinsing volume :	3 x 100 ml
Nombre de milieux test��s : Number of Environment tested :	2	Volume d'immersion de la membrane : Immersion volume of membranes :	100 ml
Conditions Conditions	Milieux de culture Environment of culture	Temp��rature d'incubation Incubation temperature	Dur��e d'incubation Incubation period
Bact��ries a��robies, levures, champignons Aerobic and fungal	Bouillon Trypcase Soja Tryptone soy solution	22,5 �� 2,5��C	14 jours 14 days
Bact��ries ana��robies et a��robies Anaerobic and aerobic	Bouillon Thioglycolate avec R��sazurine Thioglycolate Resazurine	32,5 �� 2,5��C	14 jours 14 days
Validation de la m��thode Method validation		09/OI/VAL.STE/017	

RESULTATS / RESULTS

Examen de la croissance microbienne du milieu Examination of the microbial growth in the media				
Conditions / Milieux de culture Conditions / Media of culture	Apr��s 7 jours After 7 days		Apr��s 14 jours After 14 days	
Bact��ries a��robies, levures et moisissures / Bouillon Trypcase Soja Aerobic and fungal / Tryptone soy solution	-	Positifs Positive	0	Positifs Positive
	-	N��gatifs Negative	1	N��gatifs Negative
Bact��ries ana��robies et a��robies / Bouillon Thioglycolate avec R��sazurine Anaerobic and aerobic / Thioglycolate Resazurine solution	-	Positifs Positive	0	Positifs Positive
	-	N��gatifs Negative	1	N��gatifs Negative

CONTR  LES / CONTROLS

Avant (Before)		Apr��s (After)	
Contr��le plan de travail (UFC) Work plan control (CFU)	0	0	
Air sous flux laminaire (UFC) Laminar flow air control (CFU)	0		
		Contr��le de gant (UFC) : Glove control (CFU) :	0
		Contr��le st��ril��t�� milieux : Media sterility control :	Conforme

CONCLUSION

Les   chantillons test  s ne pr  sentent pas de croissance microbienne apr  s 14 jours d'incubation
Tested products doesn't shown any microbial development after 14 days of incubation.

Aucun produit ne s'est r  v  l   positif lors de cet essai.

No Product was positive during the test.

R  dig   par : **Jennifer PAYS**
Written by :

Technicienne Biologiste
Biologist technician

Date : mercredi 29 mars 2017

Approuv   par : **Yosra HABASSI**
Approved by :

Ing  nieure support d'essais microbiologiques
Microbiological test engineer

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