Diversey	**ClearKlens Cleansinald RTU VH9S 4x5L SKU 100848253**
Batch Number	SPH31082023
Production date	08/2023
Expiration Date	01/2025

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

ClearKlens Cleansinald VH9S RTU				
Test	**Test Method**	**Specification**	**Unit**	**Results**
Appearance	PS-CON-I-029	Clear colorless liquid	N/A	Clear colorless liquid
Relative density (20°C)	PS-CON-I-027	0.990 – 1.010	-	1.000
pH (neat Solution 20°C)	PS-CON-I-040	9.0 – 11.4	-	10.9
Content of cationic substances (%)	PS-CON-I-034	0.070 – 0.090	%	0.078

Water routine test				
Microbiological Quality of WFI Water	Water PPI VRAC European pharmacopoeia	<10 cfu/100ml	CFU / 100mL	<1

Control of the Sterility of the product:

Test	**Test Method**	**Specification**	**Conformity**	**Reference number**
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	C	FR02S12751857-1-1 2013-1211A
Sterility certificate	Membrane filtration sterility testing EP 11.0 2.6.1	No Growth	C	23/CBH/STE/229

The analysis results above could change over time in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the Safety Data Sheet.

Diversey	**ClearKlens Cleansinald RTU VH9S 4x5L SKU 100848253**
Batch Number	SPH31082023
Production date	08/2023
Expiration Date	01/2025

We certify that, except for the exceptions or deviations listed above, the quoted supply has been manufactured and tested in accordance with the requirements of the specifications in force

SIMA-PHARMA Control (Responsible for the production process of the final product) :	**Stamp and signature**
Name: E. JACQUIN **Position:** General Manager **Produced on behalf of Diversey at:** Sima Pharma: Z.I. de Rousset / Peynier, 54 Av. de la Plaine, 13790 Rousset, France **Date:** 28/08/23	

End of certificate of analysis

For further information, please contact Diversey at pharma@diversey.com

ENR75-TLBS-502 C

MedicalGroup
Implant Coating Experts

Rapport N° : 23/CBH/STE/229
Report N°

Demandeur : SIMAPHARMA
Enquirer 54, avenue de la Plain ZI de Rousset
13790 ROUSSET

Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane
Test report - Membrane filtration sterilty testing

selon la Pharmacopée Européenne 11e édition chapitre 2.6.1
according to the 11th European Pharmacopoeia Edition, chepter 2.6.1

ECHANTILLON(S)/SAMPLE(S)

Informations Client / Customer informartions:

Désignation : *Product name*	ClearKlens Cleansinald RTU VH9S S	Numéro de commande : *Order number*	FBC01139
Référence client *Customer reference*	100848253	POE : *SIP*	-
Numéro de lot * *Batch number*	SPH31082023	Matériau(x) *Material*	-
Nombre d'échantillon(s) : *Sample quantity*	1	Donnée de stérilisation : *Sterilization date*	-
N° cahier des charges *N° of conditions of contract*	-		
Commentaire(s) : *Comment(s)*	10 Bidons poolés de 5 L		

Informations Medical Group / Medical Group informations:

Date de réception : *Receipt date*	mercredi 6 septembre 2023	Date de réalisation *Testing date*	mardi 12 septembre 2023

PROTOCOLE/PROTOCOL

Volume d'échantillon filtré : *Filtred sample volume*	500 ml		
Solution neutralisante : *Neutralizing solution :*	DNP + Thiosulfate	Volume de rinçage : *Rinsing volume :*	3 x 100 ml
Nombre de milieux testés : *Number of Environnement tested .*	2	Volume d'immersion de la membrane : *Immersion volume of membranes :*	100 ml

Conditions *Conditions*	Milieux de culture *Environnement of culture*	Température d'incubation *Incubation temperature*	Durée d'incubation *Incubation period*
Bactéries aérobies, levures, champignons *Aerobic and fungal*	Bouillon Trypcase Soja *Tryptone soy solution*	22,5 ± 2,5°C	14 jours *14 days*
Bactéries anaérobies et aérobies Anaerobic and aerobic	Bouillon Thioglycolate avec Résazurine Thioglycolate Resazurine	32,5 ± 2,5°C	14 jours 14 days
Validation de la méthode *Method validation*	**09/OI/VAL.STE/016a**		

RESULTATS / RESULTS

Conditions / Milieux de culture *Conditions / Media of culture*	Examen de la croissance microbienne du milieu *Examination of the microbien growth in the media*			
	Après 7 jours *After 7 days*		Après 14 jours *After 14 days*	
Bactéries aérobies, levures et moisissures / Bouillon Trypcase Soja Aerobic and fungal / Tryptone soy solution	1	Limpide/Limpid	1	Limpide/Limpid
	0	Trouble/Cloudy	0	Trouble/Cloudy
Bactéries anaérobies et aérobies / Bouillon Thioglycolate Anaerobic and aerobic / Thioglycolate Resazurine solution)	1	Limpide/Limpid	1	Limpide/Limpid
	0	Trouble/Cloudy	0	Trouble/Cloudy

CONTRÔLES /CONTROLS

Contrôle plan de travail : avant / après (UFC) *Work plan control before / after (CFU)*	0	0
Air sous flux laminaire statique / dynamique (UFC) *Laminar flow air control static / dynamic(CFU)*	0	0

Contrôle de gants gauche / droit (UFC) : *Glove control product left / right (CFU) :*	0	0
Contrôle témoins de manipulation : *Control handling indicators*	Conforme	

CONCLUSION

Les échantillons testés ne présentent pas de croissance microbienne après 14 jours d'incubation
Tested products doesn't shown any microbian 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 : *Written by* **Gloria PEISEY**
Technicienne Microbiologie
Microbiology Technician

Approuvé par : *Approved by* **Mathilde DJAALAB**
Responsable Laboratoire Microbiologie
Microbiology Laboratory Manager

Date : mercredi 27 septembre 2023

MedicalGroup
33, route de Lyon 69800 Saint-Priest - France
Tel. : +33 (0)4 72 81 22 62 - Fax : +33 (0)4 72 81 22 72

Résultats conformes
le 27/09/2023
AGRL

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 10-Jul-2023

FR02S12751857-1-1

This is to certify that Synergy Health Marcoule, 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

SIMA PHARMA
ZI
54, avenue de la Plaine
13790 ROUSSET
FRANCE

Order Information

Account Number:	142994
Synergy Health Sales Part Reference:	1135482
Customer Reference Number:	FBC01062 - 05/07/2023
Product Description:	320315P - Consommables 5L
Validation Reference:	S12119969
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	OFC000120

Irradiation Data

Date and Time of Irradiation:	08-JUL-2023 17:12
Calculated Minimum Dose kGy:	28.9
Calculated Maximum Dose kGy:	40.0

SIMA PHARMA
54 Avenue de la Plaine, ZI
13106 ROUSSET Cedex
Tél. 04 42 29 06 43 - Fax 04 42 29 06 75
SAS au capital de 1 000 €
RCS AIX 821 995 511

Reçu 10/07/23
contrôlé ok
CARRIER E.

Irradiation Release Authorised By Synergy Health Marseille SAS, a STERIS Company