

# STERANIOS 2%

Désinfectant  
de haut niveau



Laboratoires  
**ANIOS**  
Le professionnel de la désinfection

**5L**

UN08620005/LEMR-160114

# STERANIOS 2%

## High-level disinfectant

**INDICATIONS** : High level disinfectant for medical devices: surgical and medical equipment, endoscopy equipment and heat-sensitive equipment.

**COMPOSITION** : Glutaraldehyde solution [2%] buffered to pH 6, in the presence of a catalyst with effect of surface, colorant and excipients.

**MICROBIOLOGICAL PROPERTIES** : Bactericide in 5 min, 20°C [EN 13727, EN 14561]. Active against MRSA in 5 min, 20°C [EN 13727]. Mycobactericide in 10 min, 20°C [EN 14348, EN 14563]. Fungicide in 10 min, 20°C [EN 13624, EN 14562]. Viricide in 10 min, 20°C [EN 14476]. Sporicidal activity[EN 13704] has been shown for prolonged contact times.

**INSTRUCTIONS FOR USE** : Ready-to-use solution for professional use. Do not dilute. Carefully clean and rinse the medical device before soaking it in STERANIOS 2%. Cover the basin. Respect the indicated contact time for the required antimicrobial activity. Do not add any product into STERANIOS 2%. Rinse thoroughly with sterile or filtered water to eliminate any trace of the product. Dry the medical device carefully. To guarantee the efficacy of the disinfectant, check the glutaraldehyde level with a STERANIOS 2% testing strip at the start of the session, when restarting after an interruption and at least once a day. Maximum storage of the soaking bath: 30 days. Scientific dossier (efficacy, compatibility, etc.) available on request.

**PRECAUTIONS FOR USE** : DANGER. Contains glutaraldehyde. Causes serious eye irritation. Causes skin irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause respiratory irritation. Use in well-ventilated areas. Do not breathe vapours. Avoid all contact with eyes. Wear protective gloves. In case of inadequate ventilation wear respiratory protection. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Keep out of reach of children. Do not reuse the packaging. Dispose of unused product and its container as hazardous waste. Store in a well-ventilated place. Class IIb medical device. Made in France.



READY TO USE



Laboratoires Pavé du Moulin

**ANIOS**

Le professionnel de la désinfection

59260 Lille-Hellemmes - FRANCE

Tel. +33 3 20 67 67 67

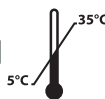
Fax +33 3 20 67 67 68

www.anios.com

LOT



CE  
0459



This product has been conceived according to a Quality organization complying with the ISO 9001 standard which is certified by AFAQ under the number 1995/3723.

GB0820005LEMV-170929



## SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

### SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product name : STERANIOS 2%  
Product code : 382000.

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Disinfection of medical devices  
For further information on product indication, please see the label.

#### 1.3. Details of the supplier of the safety data sheet

Registered company name : Laboratoires ANIOS.  
Address : PAVE DU MOULIN .59260.LILLE - HELLEMMES.FRANCE.  
Telephone : + 33 (0)3 20 67 67 67. Fax : + 33 (0)3 20 67 67 68.  
e.mail : fds@anios.com  
www.anios.com

#### 1.4. Emergency telephone number : + 33(0)1 45 42 59 59.

Association/Organisation : INRS.

### SECTION 2 : HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

##### In compliance with EC regulation No. 1272/2008 and its amendments.

Skin irritation, Category 2 (Skin Irrit. 2, H315).  
Serious eye damage, Category 1 (Eye Dam. 1, H318).  
Respiratory sensitisation, Category 1 (Resp. Sens. 1, H334).  
Skin sensitisation, Category 1 (Skin Sens. 1, H317).  
Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).  
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

##### In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Acute oral toxicity: harmful (Xn, R 22).  
Acute inhalation toxicity: harmful (Xn, R 20).  
Skin irritation (Xi, R 38).  
Serious eye damage (Xi, R 41).  
Irritant for the respiratory tract (Xi, R 37).  
Respiratory sensitisation (Xi, R 42).  
Skin sensitisation (Xi, R 43).  
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

#### 2.2. Label elements

##### In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS07



GHS05



GHS08

Signal Word :

DANGER

Product identifiers :

EC 203-856-5 GLUTARALDEHYDE

Hazard statements :

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P260 Do not breathe vapours.

P280 Wear protective gloves and eye protection/face protection.

P284 In case of inadequate ventilation wear respiratory protection.

Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Precautionary statements - Storage :

P403 Store in a well-ventilated place.

Precautionary statements - Disposal :

P501 Dispose of unused product and its container as hazardous waste.

### 2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC)  $\geq 0.1\%$  published by the European CHemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>  
No other hazard identified in the current state of knowledge.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Title for H, EUH and R indications: see § 16.

### 3.2. Mixtures

#### Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
CAS: 111-30-8 EC: 203-856-5 REACH: 01-2119455549-26 GLUTARALDEHYDE	GHS06, GHS05, GHS09, GHS08 Dgr Met. Corr. 1, H290 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Acute Tox. 3, H331 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1	T,N T;R23/25 C;R34 Xn;R42/43 N;R50	[1]	0 $\leq$ x % < 2.5

#### Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

## SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

Reminder: any unconscious person must be placed in the lateral recovery position.

### 4.1. Description of first aid measures in

#### the event of exposure by inhalation :

Move the person away from the place of exposure and take him/her outside.

In the event of respiratory problems (e.g. heavy coughing):

Put the person in a half-seated position, with the torso raised ; keep the person warm and calm.

Call a doctor immediately.

#### In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

Take care not to introduce rinsing water in the undamaged eye.

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist.

Continue rinsing until medical advice is obtained.

#### In the event of splashes or contact with skin :

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse immediately and thoroughly with water.

In the event of skin irritation, seek medical advice. Show this container or label.

#### In the event of swallowing :

Rinse out the mouth, do not allow to drink, do not induce vomiting. Calm the person down and transfer immediately to hospital or doctor. Show the label to the doctor.

### 4.2. Most important symptoms and effects, both acute and delayed

Cf. § 11

### 4.3. Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

## SECTION 5 : FIREFIGHTING MEASURES

### 5.1. Extinguishing media

#### Suitable methods of extinction

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

### 5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

### 5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

Full protective suit.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

Keep away any unprotected person.

Avoid inhaling the fumes.

Avoid all contact with skin or eyes.

### 6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Do not get rid in natural spaces (waterways, ground and vegetations...)

### 6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not collect the product for re-use.

### 6.4. Reference to other sections

Disposal considerations: see section 13.

**SECTION 7 : HANDLING AND STORAGE****7.1. Precautions for safe handling**

Product for external use - do not swallow.  
Avoid all contact with skin, eyes and clothes.  
Handle in accordance with user instructions on label

**Fire prevention :**

Handle in well-ventilated areas.  
Prevent access by unauthorised personnel.

**Recommended equipment and procedures :**

For personal protection, see section 8.  
Observe precautions stated on label and also industrial safety regulations.  
Avoid eye contact with this mixture at all times.  
Safety shower, eye bath and water point nearby.  
Change any contaminated or wet work clothes immediately.  
Ensure room is well ventilated.

**Prohibited equipment and procedures :**

No smoking, eating or drinking in areas where the mixture is used.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep the container tightly closed  
Store ONLY in the original package.  
Store between + 5 °C and + 35 °C in a dry, well ventilated place  
Do not use after the expiry date mentioned on the packaging.  
Keep out of the reach of children  
Store away from incompatible materials (see section 10)

**7.3. Specific end use(s)**

For professional use only  
Refer to paragraph 1 for product indication

**SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION**

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

The Exposure Threshold Limit Value and the Average Exposure Value given below are quoted by the CAS number of the substance. Paragraph 3 details the chemical name corresponding to the CAS number.

Individuals should not be exposed to this product if they have already experienced skin irritation or asthma caused by :

- glutaraldehyde

**8.1. Control parameters****Occupational exposure limits :**

- Belgium (Order of 19/05/2009, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.2 ppm	-	-	-	-

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
111-30-8	0.1	0.4	0.2	0.8	-	65.66

- Spain (Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Mayo 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	-	0.5 ppm	-	-	-

- Poland (2009) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.4 mg/m3	0.6 mg/m3	-	-	-

Czech Republic (Regulation No. 361/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	-	0.8 mg/m3	-	-	-

Slovakia (Regulation No. 300/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.1 ppm	0.42 mg/m3	l.		

- Switzerland (SUVA 2009) :

CAS	VME-mg/m3 :	VME-ppm :	VLE-mg/m3 :	VLE-ppm :	Temps :	RSB :
111-30-8	0,21	0,05	0,42	0,1	4x15	S

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.05 ppm	0.05 ppm	-	-	-

## 8.2. Exposure controls

### Suitable technical inspections

Ensure the rooms are well-ventilated. Atmospheric concentrations at the workplace must not exceed the limit values given for normal conditions of use.

### Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

#### - Eye / face protection

Before handling, wear safety goggles with protective sides accordance with standard EN166.

Prescription glasses are not considered as protection.

Avoid all contact with skin or eyes.

Make gloves and safety goggles with side protection available to the personnel.

Provide eye washes in workshops.

If necessary, the nearest water supply

#### - Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

When handling this product, wear suitable gloves.

Butyl or nitrile gloves are recommended.

Gloves must be replaced immediately if they show signs of wear and tear.

#### - Body protection

Avoid skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

Change wet and dirty work clothes immediately.

#### - Respiratory protection

In case of insufficient ventilation, with the risk of exceeding the TLVs (Treshold Limit Values)/TWA, wear suitable breathing apparatus.

Use Type A1P1 or A2P2 filters.

## SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### General information :

Physical state :	Fluid liquid.
Odour:	typical
Colour:	green

#### Important health, safety and environmental information

pH :	6.00 .
	Neutral.
Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	+/- 1.0
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

#### 9.2. Other information

No data available.

## SECTION 10 : STABILITY AND REACTIVITY

### 10.1. Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

## 10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

## 10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

## 10.4. Conditions to avoid

Avoid :

- frost

Do not mix with other products.

## 10.5. Incompatible materials

Latex

Refer to the scientific folder\*: product/material compatibility table

\* available on request

## 10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### 11.1.1. Substances

Not specified

#### 11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

#### Acute toxicity :

Acute toxicity estimate (ATE)\* :

Oral ATE : > 2000 mg/kg

\* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

Inhalation may lead to irritation of the respiratory tracts.

Sore throat, coughing, shortness of breath, respiratory failure

If swallowed: burns to upper digestive and respiratory tract, abdominal pain, vomiting blood, serious lesions to mucous membranes and risk of perforation.

#### Skin corrosion/skin irritation :

Skin irritation: itching, light to moderate local redness, burning sensation...

#### Serious damage to eyes/eye irritation :

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

#### Other information

Repeated or prolonged exposure may lead to sensitization by inhalation (risk of asthma) and by skin contact (risk of eczema).

## SECTION 12 : ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### 12.1.1. Substances

Not specified

#### 12.1.2. Mixtures

The mixture has not been classified as an environmental hazard, in compliance with EC regulation 1272/2008.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 12.6. Other adverse effects

No data available.



**SECTION 13 : DISPOSAL CONSIDERATIONS**

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

The packages must not be reused.

Do not pour into waterways.

**13.1. Waste treatment methods****Waste :**

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

**Soiled packaging :**

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

**Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :**

18 01 06 \* chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

**SECTION 14 : TRANSPORT INFORMATION**

Exempt from transport classification and labelling.

**SECTION 15 : REGULATORY INFORMATION****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****- Classification and labelling information included in section 2:**

Regulation (EC) No. 1272/2008 and its amendments.

**15.2. Chemical safety assessment**

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

**SECTION 16 : OTHER INFORMATION**

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any other product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

**UPDATES SINCE PREVIOUS VERSION**

- Implementation of classification and labelling in compliance with EC regulation 1272/2008.

**Title for H, EUH and R indications mentioned in section 3 :**

H290	May be corrosive to metals.
H301	Toxic if swallowed.
H301 + H331	Toxic if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
R 23/25	Toxic by inhalation and if swallowed.
R 34	Causes burns.
R 42/43	May cause sensitization by inhalation and skin contact.
R 50	Very toxic to aquatic organisms.

**Abbreviations :**

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

GHS05 : Corrosion

GHS07 : Exclamation mark

GHS08 : Health hazard

## STERANIOS 2%

STERANIOS 2% este un produs utilizat pentru STERILIZAREA materialului chirurgical și medical, endoscoapelor și a materialelor termosensibile conform cu Directiva 93/42/CE.

INDICAȚII: Steranios 2% este un sterilizant ce conține 2% glutaraldehida.

STERANIOS 2% este o soluție de glutaraldehidă stabilizată de către un complex hidroalcoolic. - controlul coroziunii metalelor feroase și neferoase, - o mai bună toleranță pentru utilizator, - un raport mai bun volatilitate/toxicitate.

MOD DE UTILIZARE: Curățați și clătiți cu grijă înainte de imersare în Steranios 2%. Acest produs nu trebuie diluat înainte de utilizare.

COMPOZIȚIE CALITATIVĂ Produsul STERANIOS 2% conține următorii compuși chimici: Glutaraldehyda 2,00 %, Methanol, Propan-2-ol, Methoxypropoxypropanol.

PROPRIETĂȚI MICROBIOLOGICE STERANIOS 2% este un produs testat conform următoarelor Norme EN și AFNOR de eficacitate antimicrobiană: Bactericid : conform EN 1040 ; EN 13727 ; EN 14561; Micobactericid: EN 14348; EN 14563 Fungicid: EN 1275 ;EN 13624; EN 14562; Sporicid : B.Cereus ; B.Subtilis; Cl.Sporogenes ; Cl Difficile; Virucid : EN 14476; HIV-1 ; HBV; BVDV(HCV).

PREZENTARE: Cutie: 4 flacoane x 5 l

Clasificarea substanței: Conform regulamentului (CE) nr. 1272/2008 și modificărilor sale.



GHS07



GHS05



GHS08

**Pictograme de pericol :**

Cuvânt de avertizare : PERICOL

Identificatorii de produs :EC 203-856-5 GLUTARAL. Fraze de pericol :H290 Poate fi corosiv pentru metale. H302 + H332 Nociv în caz de înghițire sau inhalare. H314 Provoacă arsuri grave ale pielii și lezarea ochilor. H317 Poate provoca o reacție alergică a pielii. H334 Poate provoca simptome de alergii sau astm sau dificultăți de respirație în caz de inhalare. H335 Poate provoca iritarea căilor respiratorii. H412 Nociv pentru mediul acvatic cu efecte pe termen lung. Fraze de precauție -Generale :P102 A nu se lăsa la îndemâna copiilor. Fraze de precauție - Prevenire : P260 Nu inspirați vaporii. P273 Evitați dispersarea în mediu. P280 Purtați mănuși de protecție/îmbracaminte de protecție/echipament de protecție a ochilor/echipament de protecție a feței. P284 În cazul în care ventilația este insuficientă, purtați echipament de protecție respiratorie. Fraze de precauție - Intervenție :P301 + P330 + P331 ÎN CAZ DE ÎNGHIȚIRE: clătiți gura. NU provocați vomă. P303 + P361 + P353 ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateți imediat toată îmbracaminta contaminată. Clătiți pielea cu apă/faceti dus. P304 + P340 ÎN CAZ DE INHALARE: transportați persoana la aer liber și mențineți-o într-o poziție confortabilă pentru respirație. P305 + P351 + P338 ÎN CAZ DE CONTACT CU OCHII: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. P310 Sunați imediat la un CENTRU DE INFORMARE TOXICOLOGICĂ sau un medic. P342 + P311 În caz de simptome respiratorii: sunați la un CENTRU DE INFORMARE TOXICOLOGICĂ sau un medic. Fraze de precauție - Depozitare : P403 A se depozita într-un spațiu bine ventilat. Fraze de precauție - Eliminare : P501 Produsul neutilizat și ambalajul sau trebuie îndepărtate ca deșeurile periculoase.

**Producător: LABORATOIRES ANIOS**

Adresa: Pave du Moulin 59260, Lille-Hellemmes, Franța

Tel: +33 3 20 67 67 67 Fax: +33 3 20 67 67 68 [www.anios.com](http://www.anios.com)

**GMED certifie que le système de management de la qualité développé par**  
*GMED certifies that the quality management system developed by*  
**GMED certifica que el sistema de gestión de la calidad adoptado por**

**LABORATOIRES ANIOS**  
**Pavé du moulin**  
**59260 LILLE-HELLEMMES FRANCE**

**pour les activités / for the activities / para las actividades**

**Conception, développement, fabrication, prestations associées et vente de produits antimicrobiens,  
détergents et matériels pour procédés de désinfection de dispositifs médicaux  
dédiés aux hôpitaux et cliniques.**

*Design, development, manufacturing, servicing and sales of antimicrobial products, detergents and materials  
for disinfecting processes of medical devices dedicated to hospitals and clinical sectors.*

**Diseño, desarrollo, fabricación, servicios y venta de productos antimicrobianos, detergentes y materiales  
para los procesos de desinfección de dispositivos médicos dedicados a hospitales y clínicas.**

**réalisées sur le(s) site(s) de / performed on the location(s) / que se realizan en**

**LABORATOIRES ANIOS**  
**Pavé du Moulin 59260 LILLE-HELLEMMES FRA**  
**LABORATOIRES ANIOS**  
**3330 rue de Lille 59262 SAINGHIN-EN-MELANTOIS FRA**

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*  
**es conforme a las exigencias de las normas internacionales**

**ISO 13485 : 2016 - NF EN ISO 13485 : 2016**

**Début de validité / Effective / Fecha efectiva August 3rd, 2018 (included)**

**Valable jusqu'au / Expiry date / Fecha de expiración June 10th, 2021 (included)**

**Etabli le / Issued on / Fecha de preparación August 3rd, 2018**



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**





**LNE**

Le service, une prestation à part entière

Certification  
Médical-Serwis

Notified Body N° 0459

**ATTESTATION / CERTIFICATE / CERTIFICADO n° 31390 rev. 5**  
Délivrée à Paris le 12 juin 2018  
Issued in Paris on June 12th, 2018  
Establecido en Paris, el 12 junio 2018

## ATTESTATION CE / EC CERTIFICATE / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

Aprobación del sistema completo de Seguro de la calidad

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

**ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices**

**ANEXO II excluyendo el punto 4 Directiva 93/42/CEE relativa a los productos sanitarios**

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

**For class III devices, a EC design certificate is required**

Fabricant / Manufacturer / Fabricante

**LABORATOIRES ANIOS**

**Pavé du Moulin**

**59260 LILLE-HELLEMMES FRANCE**

Catégorie du(des) dispositif(s) / Device(s) category / Categoría del producto

**Détergents désinfectants ou désinfectants pour DM Invasifs et/ou non invasifs.**

*Detergent disinfectant or disinfectant for invasive and/or non invasive devices.*

**Détergents desinfectantes o desinfectantes para DM invasivos y/o no invasivos**

*Voir détails sur addendum / See attachment for additional information*

**Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177315, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

**LNE/G-MED certifies that, on the basis of the results contained in the file referenced P177315, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.**

**El LNE/G-MED certifica que después del examen de los resultados indicados en el expediente P177315, el sistema de calidad para el diseño, la fabricación y el control final - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo II excluyendo el punto 4 de la Directiva 93/42/CEE.**

**La validité du présent certificat est soumise à une vérification périodique ou imprévue**  
**The validity of the certificate is subject to periodic or unexpected verification**

**Début de validité / Effective date / Fecha efectiva : June 11th, 2018 (included)**

**Valable jusqu'au / Expiry date / Fecha de expiración : June 10th, 2021 (included)**



On behalf of the G-MED Certification Director

G-MED Certification Technical Director

Por delegación para el Director de Certificación G-MED

LNE - 31390 rev. 5  
Renouvelle le certificat 31390-4  
GMED\_5293\_ESP-V3-01-2013

**Laboratoire national de métrologie et d'essais** • Établissement public à caractère industriel et commercial  
LNE/G-MED • Organisme notifié n° 0459

1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

**Identification des dispositifs / Identification of devices / Identificación de los dispositivos**

Les produits couverts par ce certificat sont référencés sur le document  
daté du 10 avril 2018 (11 pages), authentifié par le LNE/G-MED le 03 mai 2018

*Medical devices covered by this certificate are referenced on the manufacturer's list of products  
dated April 10<sup>th</sup>, 2018 (11 pages) authenticated by LNE/G-MED on May 3<sup>rd</sup>, 2018*

Los productos cubiertos por este certificado están referenciados sobre el documento  
del 10 de abril de 2018 (11 páginas) autenticado por LNE/G-MED el 3 de mayo de 2018

**Ce certificat couvre le site et les activités suivantes :**

*This certificate covers the following site and activities:*

Este certificado cubre el sitio y las actividades siguientes:

- **LABORATOIRES ANIOS – Pavé du Moulin 59260 LILLE-HELLEMES FRANCE**  
Siège social – Activités de conception, de fabrication et de contrôle final  
Headquarters – Design, manufacturing and final inspection activities  
Domicilio social – Actividades de diseño, de fabricación y de control final

LNE/G-MED 0459



On behalf of the G-MED Certification Director  
Béatrice LYS  
G-MED Certification Technical Manager  
Por delegación para el Director de Certificación

ADD

Laboratoire national de métrologie et d'essais

LNE/G-MED • Exploitation Médicale • IMAVA  
1, rue de la République • F-59000 Lille • France • Tél. : +33 (0)3 20 37 94 00 • Fax : +33 (0)3 20 37 94 01 • www.lne.fr • lne@gm-med.fr

720 DM 0701-31 rev 5 du 28/07/2015





# LNE

Le progrès, une passion à partager

Centre National  
de Mesure

Addendum au certificat n° 31390 rev. 5  
Addendum of the certificate n° 31390 rev. 5  
Addendum al certificado n° 31390 rev. 5  
Dossier / File / Expediente N° P177315

page 1/2

## Catégorie du (des) dispositifs / Device(s) category / Categoría del producto :

### Version française :

Détergents désinfectants ou désinfectants pour DM Invasifs et/ou non Invasifs :

- Désinfectants Circuits dialyse
- Désinfectants manuels et/ou machines pour DM Invasifs
- Détergents Désinfectants manuels et/ou machines pour DM Invasifs
- Détergents Désinfectants manuels et/ou machines pour DM non Invasifs
- Sprays détergents désinfectants ou désinfectants pour DM Invasifs
- Sprays détergents désinfectants ou désinfectants pour DM non Invasifs
- Lingettes détergentes désinfectantes ou désinfectantes pour DM Invasifs
- Lingettes détergentes désinfectantes ou désinfectantes pour DM non Invasifs

### Version anglaise :

Detergents disinfectants or disinfectants for invasive and/or non-invasive devices :

- Disinfectants for dialysis circuits
- Disinfectant for manual use and/or automatic machines for invasive devices
- Detergent disinfectant for manual use and/or automatic machines for invasive devices
- Detergent disinfectant or disinfectant sprays for non-invasive devices
- Detergent disinfectant or disinfectant sprays for non-invasive devices
- Detergent disinfectant or disinfectant wipes for invasive devices
- Detergent disinfectant or disinfectant wipes for non-invasive devices

### Version espagnole:

Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos :

- Desinfectantes para circuitos diálisis,
- Desinfectantes manuales y/o máquinas para DM invasivos,
- Detergentes desinfectantes manuales y/o máquinas para DM invasivos
- Detergentes desinfectantes manuales y/o máquinas para DM no invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM Invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM no Invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM Invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM no Invasivos

LNE/G-MED 0459



On behalf of the G-MED Certification Director  
Béatrice LYS  
G-MED Certification Technical Manager  
Por delegación para el Director de Certificación

ADD

720 DM 07/01-31 rev 5 du 28/07/2015

LNE/G-MED (0459) reconnaît que son certificat CE est  
valide pour les dispositifs médicaux décrits  
A. Pevel  
03 MAI 2018  
LNE/G-MED (0459) recognizes that its EC certificate  
is valid for the medical devices listed  
1111

## ATTESTATION CE / EC CERTIFICATE / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System / Aprobación del sistema completo de Seguro de la calidad

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux / Annex II excluding section 4 directive 93/42/EEC concerning medical devices / ANEXO II excluyendo el punto 4 directiva 93/42/CEE relativa a los productos sanitarios  
Pour les dispositifs de classe III, un certificat CE de conception est requis / For class III devices, a EC design certificate is required.

Fabricant / Manufacturer / Fabricante

**LABORATOIRES ANIOS**

**Pavé du Moulin**

**59260 LILLE-HELLEMMES France**

### Catégorie du (des) dispositifs / Device(s) category / Categoría del producto :

- Desinfectants circuits dialyse, *Disinfectants for dialysis circuits*, Desinfectantes para circuitos diálisis
- Desinfectants manuels et/ou machines pour DM invasifs, *Disinfectants for manual use and/or automatic machines for Invasive devices*, Desinfectantes manuales y/o máquinas para DM invasivos
- Détergents désinfectants manuels et/ou machines pour DM invasifs, *Detergent disinfectant for manual use and/or automatic machines for Invasive devices*, Detergentes desinfectantes manuales y/o máquina para DM invasivos
- Détergents désinfectants manuels et/ou machines pour DM non invasifs, *Detergent disinfectant for manual use and/or automatic machines for non invasive devices*, Detergentes desinfectantes manuales y/o máquina para DM no invasivos
- Sprays détergents désinfectants ou désinfectants pour DM invasifs, *Detergent disinfectant or disinfectant sprays for Invasive devices*, Pulverizadores detergentes desinfectantes o desinfectantes para DM invasivos
- Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices*, Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos
- Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs, *Detergent disinfectant or disinfectant wipes for Invasive devices*, Toallitas detergentes desinfectantes o desinfectantes para DM invasivos
- Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs, *Detergent disinfectant or disinfectant wipes for non invasive devices*, Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos

10/04/2018







## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Der	Введите текст для поиска...								
I.3. Cer CE	Cer CE	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin
I.2. Dec de con CE	Dec de con CE							anios		
		DM000241048	DEZINFECTANT PENTRU INSTRUMENTAR MEDICAL ȘI CHIRURGICAL	ACTANIOS LDI	5 L	1987369	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	Rg04-000275
		DM000241052	BANDELETE DE CONTROL AL DILUȚIEI DEZINFECTANTULUI	ANIOSEPT ACTIV	50 PCS.	100409	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	Rg04-000275
		DM000208381	DEZINFECTANT PENTRU STERILIZAREA LA RECE A DISPOZITIVELOR MEDICALE	WIP'ANIOS EXCEL			Franta	LABORATOIRES ANIOS	ERICON S.R.L.	Rg04-000118
		DM000017737	DEZINFECTANT PENTRU STERILIZAREA LA RECE A DISPOZITIVELOR MEDICALE	ANIOSEPT ACTIV	5 KG	1896	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-14
		DM000197603	DEZINFECTANT PENTRU STERILIZAREA LA RECE A DISPOZITIVELOR MEDICALE	ANIOSEPT ACTIV	1 KG	1896	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-14
		DM000021788	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	5 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-96
		DM000021789	DEZINFECTANT DE NIVEL ÎNALT PENTRU STERILIZARE LA RECE	ANIOXIDE 1000	5 L, ACTIVATOR	1081.299	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-96
		DM000021787	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	1 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-96
		DM000021766	DEZINFECTANT PENTRU DISPOZITIVE MEDICALE NON-INVAZIVE	ANIOSPRAY QUICK	1 L	2084.073	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-83
		DM000019357	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	SURFANIOS PREMIUM	LICHID, 5 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-24