



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	Введите текст для поиска...								
		Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin
II.2. Etiche (etich dispoz medic și al amba	Etiche			aniosyme				anios		
		DM000021788	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	5 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-96
I.3. Certificate	Certificate	DM000021787	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	1 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-96
II.3. Instrumente de utilizare	Instrumente de utilizare	DM000017740	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR	ANIOSYME SYNERGY 5	5 L	2235000	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-24!
		DM000017739	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR	ANIOSYME SYNERGY 5	1 L	2235000	Franta	LABORATOIRES ANIOS	ERICON S.R.L.	A07.PS-01.Rg04-24!
II.2. Etiche (etich dispoz medic și al amba	Etiche	Содержит('Producatorul','anios') И Содержит('NameMake','aniosyme')								
II.2. Etiche (etich dispoz medic și al amba	Sticke									
I.2. Declarații de conformanță	Declarații de conformanță									



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...								
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin
						soluscope		
DM000017265	DETERGENT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELOR	SOLUSCOPE NW	5 L		Franta	SOLUSCOPE SAS	ERICON S.R.L.	A07.PS-01.Rg04-24
DM000017267	DEZINFECTANT DE NIVEL ÎNALT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELOR	SOLUSCOPE GTA	5 L		Franta	SOLUSCOPE SAS	ERICON S.R.L.	A07.PS-01.Rg04-24
DM000017266	REPROCESOR AUTOMAT PENTRU DEZINFECTAREA ENDOSCOAPELOR, VERSIUNE SOFTWARE SL-V1 V 4.0.0.	SOLUSCOPE	SERIE 1, SL-V1-GTA		Franta	SOLUSCOPE SAS	ERICON S.R.L.	A07.PS-01.Rg04-24
Содержит('Producatorul', 'soluscope')								

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

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.

Detergentes 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



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
- Disinfectants for manual use and/or automatic machines for invasive devices
- Detergent disinfectant for manual use and/or automatic machines for invasive devices
- Detergent disinfectant for manual use and/or automatic machines for non-invasive devices
- Detergent disinfectant or disinfectant sprays for 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:

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

- Desinfectantes para circuitos diálisis,
- Desinfectantes manuales y/o máquinas para DM invasivos,
- Desinfectantes manuales y/o máquinas para DM invasivos
- Détergents desinfectantes manuales y/o máquinas para DM no invasivos
- Pulverizadores desinfectantes o desinfectantes para DM invasivos
- Pulverizadores desinfectantes o desinfectantes para DM no invasivos
- Toallitas desinfectantes o desinfectantes para DM invasivos
- Toallitas 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 0701-31 rev 5 du 28/07/2015

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 10th, 2018 (11 pages) authenticated by LNE/G-MED on May 3rd, 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 suivants :
This certificate covers the following site and activities:
Este certificado cubre el sitio y las actividades siguientes:

- **LABORTAOIRES 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

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



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 :

- Désinfectants circuits dialyse, *Disinfectants for dialysis circuits, Desinfectantes para circuitos diálisis*
- Désinfectants 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




CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ
AL PRODUSULUI BIODISTRUCTIV

Nr. 00300 data/luna/anul 13/06/2018

Solicitant: For titular „Ericon” S.R.L.

Adresa juridică: str. Vasile Lupu 6, Durlești, mun. Chișinău, Republica Moldova

Nr. de identificare de stat – codul fiscal 1003600000316

În conformitate cu HG nr. 546 din 10.09.09 și în baza ordinului Ministerului Sănătății, Muncii și Protecției Sociale nr. 731 din 13.06.2018
(nr. data/luna/anul)

emis în baza documentației înaintate, s-a decis că următorul produs biodistructiv poate fi fabricat sau comercializat și utilizat în Republica Moldova, conform prevederilor legislației în vigoare.

Denumirea comercială a produsului: DERMANIOS SCRUB Chlorhexidine 4%

1. Date de identificare ale produsului:

1.1 Categoria de produs: biodistructiv

- Grupa principală: 1

- Tip de produs: 1

1.2 Utilizare: Săpun antiseptic pentru spălarea mâinilor și corpului.

1.3 Forma de condiționare și ambalare: Lichid, sticle, butelii cu pompă și canistre de 2 și 5L

1.4 Conținut în substanțe active: Digluconat de chlorhexidină – 4%

1.5 Categoriile de utilizatori: profesionali

1.6 Informații privind reglementările aplicabile: HG nr. 564 din 10.09.2009, Ordinul MS nr.299 din 06.05.2010 cu modificările ulterioare.

2. Date de identificare ale producătorului:

2.1 Firma: Laboratoires ANIOS

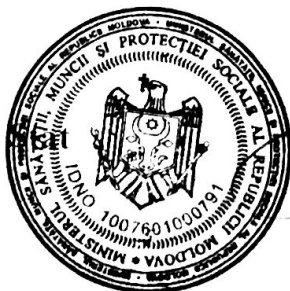
2.2 Adresa: Pave Du Moulin, 59260, Lille – Hellemmes, Franța

Valabilitatea certificatului de înregistrare data/luna/anul 13/06/2023

Compoziția, parametrii de calitate ai produsului și domeniul de utilizare sunt cei prevăzuți în documentația tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. 300 din 08.06.2018.

Orice modificare a datelor de identificare a produsului biodistructiv, duce în mod automat la anularea certificatului de înregistrare.

Secretar de



Aliona SERBULENCO



EC CERTIFICATE

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
13400 AUBAGNE – FRANCE

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

The design, manufacture of washer-disinfectors for endoscopes or TEE probes, disinfectant and cleaning solutions, consumables and accessories

Device Classification:

IIb

Device Descriptions:

Washer-disinfectors for endoscopes or TEE probes, disinfectant and cleaning solutions, consumables and accessories

Model Type:

See Attachment 1

Manufacturing/Off Sites located at:

199, Avenue de Jouques
ZI Les Paluds, 13400 Aubagne
France

We hereby declare that an examination of the full quality assurance system has been carried out per report 11756157, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 2 attachments listing model numbers.

File Number	A14025	Cycle Start Date	07 September 2017
Certificate No.	537.170907	Effective Date	07 September 2017
		Expiry Date	06 September 2022

Authorised by

Deborah Stubbs
Certification Reviewer

For and on Behalf of UL International (UK) Ltd

Notified Body

0843



EC CERTIFICATE

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
13400 AUBAGNE – FRANCE

Attachment 1 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Flexible Endoscope washer/disinfectors	SOLUSCOPE SERIE 4 PA	SL-V4-PA used with Soluscope CLN and Soluscope PAA	IIb	35628 (endoscopes washer/disinfectors)
		SL-V4-SA-PA used with Soluscope CLN and Soluscope PAA	IIb	
		SL-V4-RO-PA used with Soluscope CLN and Soluscope PAA	IIb	
	SOLUSCOPE SERIE ENT	SL-ENT used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	
	SOLUSCOPE SERIE 3	SL-V3-GTA used with Soluscope C+ and Soluscope D	IIb	
		SL-V3-PA used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	
SOLUSCOPE SPRINT	SL-V3-PA-G used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb		

File Number A14025
Certificate No. 537.170907

Cycle Start Date 07 September 2017
Effective Date 07 September 2017
Expiry Date 06 September 2022

Authorised by

Deborah Stubbs
Certification Reviewer
For and on Behalf of UL International (UK) Ltd

Notified Body

0843



EC CERTIFICATE

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
13400 AUBAGNE – FRANCE

Attachment 2 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
	SOLUSCOPE SERIE 1	SL-V1-PA used with Soluscope EZ or Soluscope NW and Soluscope PA	IIb	35628 (for endoscopes washer/disinfector)
		SL-V1-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA	IIb	
		SL-V1-120-PA used with Soluscope EZ or Soluscope NW and Soluscope PA	IIb	
		SL-V1-120-GTA used with Soluscope EZ or Soluscope NW and Soluscope GTA	IIb	
		SL-V1-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA	IIb	
		SL-V1-120-OPA used with Soluscope EZ or Soluscope NW and Soluscope OPA	IIb	
TEE probes washer/disinfectors	SOLUSCOPE SERIE TEE	SL-TEE used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	61673 (TEE probes washer-disinfector)

File Number A14025
Certificate No. 537.170907

Cycle Start Date 07 September 2017
Effective Date 07 September 2017
Expiry Date 06 September 2022

Authorised by

Deborah Stubbs
Certification Reviewer
For and on Behalf of UL International (UK) Ltd

Notified Body
0843



CERTIFICATE OF REGISTRATION

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
Aubagne 13400 FRANCE

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016

EN ISO 13485:2016

The design, manufacture and servicing of endoscope and TEE probes reprocessors. The design and manufacture of disinfectant and cleaning solutions, consumables and accessories. The design, manufacture and servicing of drying and storage cabinets for flexible endoscopes. The manufacture of plastic components for endoscope and TEE probe reprocessors and for drying and storage cabinets. The provision of technical support for endoscope and TEE probe reprocessing. The installation and servicing of sterilizers intended for rigid endoscopes and surgical instruments.

With additional locations listed on Addendum: 1



Authorized by

Michael J. Windler, P.E.

Manager of Global Regulatory Service

Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC



Check Certificate
Status: [here](#)

File Number	A14025	Cycle Start	January 18, 2019
Certificate Number	2407.190118	Effective Date	January 18, 2019
Initial Issue Date	January 18, 2019	Expiry Date	September 6, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



CERTIFICATE OF REGISTRATION

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
Aubagne 13400 FRANCE

Addendum 1

1-2

**199, Avenue de Jouques
Aubagne FRANCE**

Performing: HHRR, CS, Sales&Marketing, Finances, Top management, Production of plastic parts, Production of cabinets

File Number	A14025	Cycle Start	January 18, 2019
Certificate Number	2407.190118	Effective Date	January 18, 2019
Initial Issue Date	January 18, 2019	Expiry Date	September 6, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA