



# 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



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## Soluscope SAS

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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		

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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	
<b>TEE probes washer/disinfectors</b>	SOLUSCOPE SERIE TEE	SL-TEE used with Soluscope C+ and Soluscope P and its additive Soluscope A	IIb	61673 (TEE probes washer-disinfector)

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**Notified Body**  
**0843**



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# CERTIFICATE OF COMPLIANCE

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Salesorder 54193936	Invoice 62062945	Customer 10833795	Purchase Order	Date 27-MAR-2018	Page 1	MSC # 0
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A68N

Quantity	Item Number/Information	Manufacturer
2	PE150AF-ND PE150AF COUNTRY/ORIGIN: USA	EXCELITAS TECHNOLOGIES [CI]

The Digi-Key products included in the above shipment were purchased from the original manufacturer or through the manufacturer's authorized distribution. The original manufacturer warrants and certifies that the products they produce meet their specifications. Test reports (chemical, physical, electrical, etc.) supporting their certification are on file (either here or in the plant of the manufacturer) and will be made available upon request. This document is evidence of Conformity that this shipment meets the requirements of Digi-Key's Quality Management System and/or Purchase Order requirements agreed on between the customer and Digi-Key.

This certification is valid only to the original customer and is not transferable.

If you have any questions, please contact Customer Service at 800-858-3616.

Kim Gilbert, Director, Customer Service



# CERTIFICATE OF REGISTRATION

## Soluscope SAS

100 rue du Fauge  
ZI Les Paluds  
13400 Aubagne 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 13485:2003 / Cor 1:2009 EN ISO 13485:2012

The design, manufacture and servicing of endoscope and TEE probes reproprocessors. 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 reproprocessors 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 a Manufacturing Site located at:

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

The Manufacturing Site at 199, Avenue de Jouques performs: Manufacture of plastic components and drying and storage cabinets.

File Number A14025  
Certificate No. 11756157.PDWS

Effective Date September 7, 2017  
Expiry Date February 28, 2019

Authorized by

**Michael J. Windler, P.E.**  
Manager of Global Regulatory Service  
Distinguished Member of the Technical Staff  
UL Life and Health Sciences  
UL LLC



Validate Certificate:  
[here](#)

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