



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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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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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)

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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

EC Declaration of Conformity

No. of certificate : No 20131114-DCSP001

Manufacturer's Name : SOMETECH INC.



Manufacturer's Address : (Ace High-end Tower II, Guro-dong) 1201ho, 61, Digital-ro 26gil,
Seoul Korea

declares, that the product

Product Name : Medical camera system

Model Name :VES-100 (LED)

Classification Class I
(according to the Rule 9 of Classification Criteria, annex IX,
MDD 93/42/EEC)

Applicable Harmonized - EN 60601-1 [1990] Medical electrical equipment

Standard Part1: General requirements

- EN 60601-1-2 [2001] Medical electrical equipment

Part1: General requirements Section1.2 Collateral standard:
Electromagnetic compatibility

The product herewith complies with the requirements of the MD Directive 93/42/EEC and carries the "CE" mark accordingly.



Seoul, Korea Nov 14, 2018

Sometech Inc.

A handwritten signature in blue ink, appearing to read "Hee-Bong Yang".

Hee-Bong Yang / President

(President, on behalf of Sometech Inc.)