



# CERTIFICATE

**EC Certificate No. 1434-MDD-420/2021**

**Full Quality Assurance System**

**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Soluscope SAS**

**100 rue du Fauge**

**ZI Les Paluds**

**Aubagne 13400 FRANCE**

for the design, manufacture and final inspection of  
medical devices, class IIb

**Washer-disinfectors for endoscopes or TEE probes and disinfectant  
solutions**

*The list of medical devices covered by this certificate is provided in the annex 1*

complies with requirements  
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: **from 25.05.2021 to 26.05.2024**

The date of issue of the Certificate: **25.05.2021**

The date of the first issue of the Certificate: **26.04.2019**

**CE 1434**

Issued under the Contract No. MD-15/2020, MD-33/2021

Application No: 642/2020, 520/2021

Certificate bears the authorized person signature.

Warsaw, 25/05/2021

Module H2/3/4/5

FBM-26-E\_9

*Ampe*  
Vice-President



# ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-420/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Chemicals	Anticorrosive additive to be used with disinfectant Soluscope P	Soluscope A
	Disinfectant to be used with Soluscope SERIE 1	Soluscope PA
		Soluscope GTA
		Soluscope OPA
	Disinfectant to be used with Soluscope Serie 3	Soluscope D
	Disinfectant to be used with Soluscope SERIE 3, SPRINT, SPRINT PT, SERIE ENT, SERIE TEE	Soluscope P
	Disinfectant to be used with Soluscope SERIE 4 PA	Soluscope PAA
Predisinfectant to be used with Soluscope SERIE 3, SPRINT, SPRINT PT, SERIE ENT, SERIE TEE	Soluscope C+	
Flexible Endoscope washer/disinfectors	SOLUSCOPE SERIE 1	SL-V1-PA
		SL-V1-120-PA
		SL-V1-GTA
		SL-V1-120-GTA
		SL-V1-OPA
		SL-V1-120-OPA
		SL-V1-AL-PA
		SL-V1-AL-GTA
	SOLUSCOPE SERIE 4 PA	SL-V4-PA
		SL-V4-SA-PA
		SL-V4-RO-PA
	SOLUSCOPE SERIE ENT	SL-ENT
	SOLUSCOPE SPRINT	SL-V3-PA-G
	SOLUSCOPE SPRINT PT	SL-V3-PA-G-PT
		SL-V3-PA-PT
TEE probes washer/disinfectors	SOLUSCOPE SERIE TEE	SL-TEE



Issued under the Contract No. MD-15/2020, MD-33/2021  
 Application No: 642/2020, 520/2021  
 Certificate bears the authorized person signature.  
 Warsaw, 25/05/2021

*Amber*  
 Vice-President



# Polish Centre for Testing and Certification

Warsaw, 2021-07-08

Letter No.: PCBC.BM.958.2021.DP

**Soluscope SAS**  
**100 rue du Fauge**  
**ZI Les Paluds**  
**Aubagne 13400 FRANCE**

*To whom it may concern,*

PCBC would like to inform that the certificate number **1434-MDD-420/2021** has been changed. The scope of the certificate has been changed from "Washer-disinfectors for endoscopes or TEE probes, disinfectants and cleaners, consumables and accessories" to "Washer-disinfectors for endoscopes or TEE probes and disinfectant solutions".

Updated certificate will be sent by courier and is valid until 2024-05-26.

The certificate sent by e-mail on May 25, 2021 is considered invalid.

*Kind regards,*

Elektronicznie  
podpisany przez  
Monika Elżbieta  
Mroczkiewicz  
Data: 2021.07.08  
14:09:49 +02'00'

*Monika Mroczkiewicz*

*Director of Medical Devices*

*Certification Department*

*PCBC, NB 1434*

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# Polish Centre for Testing and Certification

BM.433.517.2022.1086.EW  
BM.433.520.2021.1086.22.EW

Warsaw, 2022-06-24

**Soluscope SAS**  
**100 rue du Fauge**  
**ZI Les Paluds**  
**Aubagne 13400 FRANCE**

To whom it may concern,

Polish Centre for Testing and Certification declares that the information in EC certificate No. 1434-MDD-420/2021 has been updated by removal of SOLUSCOPE SERIE 1 SL-V1-OPA, SOLUSCOPE SERIE 1 SL-V1-AL-OPA, SOLUSCOPE SERIE 1 SL-V1-120-OPA, SOLUSCOPE SERIE 1 SL-V1-120-PA, SOLUSCOPE SERIE 1 SL-V1-120-GTA, Disinfectant to be used with Soluscope SERIE 1 Soluscope OPA and addition of SOLUSCOPE SPRINT PT SL-V3-RO-PA-PT, SOLUSCOPE SPRINT PT SL-V3-RO-PA-G-PT.

The update introduced does not constitute a significant change in the design or intended purpose in accordance with Article 120(3) of Regulation 2017/745 and the EC certificates number 1434-MDD-420/2021 issued on 25.05.2021 remain valid until 26.05.2024.

*Sincerely,*

*Tomasz Koeber*

Elektronicznie podpisany  
przez Tomasz Artur Koeber  
Data: 2022.06.24 15:00:08  
+02'00'

*Director of Medical Devices Certification Department  
Polish Centre for Testing and Certification*

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