

# EC Certificate

**Full Quality Assurance System**  
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 2027206-1

Manufacturer: SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road, Yuehai Subdistrict,  
Nanshan District, Shenzhen  
518057 Guangdong  
P.R. China

Products: Ultrasonic Diagnostic Systems, Medical Endoscope Systems

  
**TÜVRheinland**<sup>®</sup>

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 10918672-100

Effective date: 2021-04-16

Expiry date: 2024-05-26

Issue date: 2021-04-16



Dipl.-Ing. W. Hsu  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

# EC Certificate

## Full Quality Assurance System

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2027206-1

Manufacturer: SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
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1 Keji Middle 2nd Road, Yuehai Subdistrict,  
Nanshan District, Shenzhen  
518057 Guangdong  
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	SONOSCAPE MEDICAL CORP. 4/F(B), 1/F(S), 5/F, Nanfeng Building Nanshan Yungu Innovation Industrial Park, 4093 Liuxian Blvd., Taoyuan Subdistrict, Nanshan Shenzhen 518055 Guangdong P.R. China	Ultrasonic Diagnostic Systems, Medical Endoscope Systems
/02	SONOSCAPE MEDICAL CORP. Room 201 & 1401, A4 Building, Nanshan Intelligence Park, 1001 Xueyuan Blvd, Taoyuan Subdistrict, Nanshan District, Shenzhen, 518071 Guangdong P.R. China	Ultrasonic Diagnostic Systems, Medical Endoscope Systems

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# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2027206-1


Organization: SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road,  
Yuehai Subdistrict, Nanshan District,  
Shenzhen  
518057 Guangdong  
P.R. China

Scope: Design and Development, Manufacture and Distribution of Medical  
Endoscope Systems, and Ultrasonic Diagnostic Systems;  
Design and Development, Manufacture and Distribution of In-Vitro  
Diagnostic Analysers, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic  
Reagents, Calibrators and Controls used in determination of Inflammatory  
Diseases Markers, determination or monitoring of Physiological Markers for  
a Specific Disease, and the analysis of Haematology

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10919683-100  
Effective date: 2022-04-23  
Expiry date: 2025-04-22  
Issue date: 2022-04-14



  
Jason Pan  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 2027206-1

Organization: SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road,  
Yuehai Subdistrict, Nanshan District,  
Shenzhen  
518057 Guangdong  
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o SONOSCAPE MEDICAL CORP. Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen 518057 Guangdong P.R. China	Distribution of Medical Endoscope Systems, Ultrasonic Diagnostic Systems; In-Vitro Diagnostic Analysers, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Reagents, Calibrators and Controls used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology
/02	c/o SONOSCAPE MEDICAL CORP. 4/F(B), 1/F(S), 5/F, Nanfeng Building, Nanshan Yungu Innovation Industrial Park, 4093 Liuxian Blvd., Taoyuan Subdistrict, Nanshan, Shenzhen, 518055 Guangdong P.R. China	Manufacture of Medical Endoscope Systems, Ultrasonic Diagnostic Systems; In-Vitro Diagnostic Analysers used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology

Report No.: 10919683-100  
Effective date: 2022-04-23  
Expiry date: 2025-04-22  
Issue date: 2022-04-14



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# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

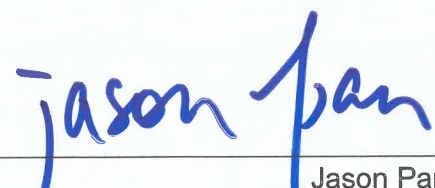
Registration No.: SX 2027206-1

Organization: SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road,  
Yuehai Subdistrict, Nanshan District,  
Shenzhen  
518057 Guangdong  
P.R. China

The scope of certification also covers the following:

- |     |   |  |
|-----|---|--|
| /03 | c/o SONOSCAPE MEDICAL CORP.<br>1/F(B) , Building A3 in Xinjianxing<br>Technical Industrial Park, Fengxin Road,<br>Loucun Community, Gongming<br>Subdistrict, Guangming New<br>District, Shenzhen,<br>518107 Guangdong<br>P.R. China | Manufacture of In-Vitro Diagnostic Test Kits,<br>In-Vitro Diagnostic Reagents, Calibrators and<br>Controls used in determination of<br>Inflammatory Diseases Markers,<br>determination or monitoring of Physiological<br>Markers for a Specific Disease, and the<br>analysis of Haematology  |
| /04 | c/o SONOSCAPE MEDICAL CORP.<br>Room 201 & 1401,<br>A4 Building, Nanshan Intelligence Park,<br>1001 Xueyuan Blvd, Taoyuan Subdistrict,<br>Nanshan District, Shenzhen,<br>518071 Guangdong<br>P.R. China                              | Design and Development of Medical<br>Endoscope Systems, Ultrasonic Diagnostic<br>Systems; In-Vitro Diagnostic Analysers, In-<br>Vitro Diagnostic Test Kits, In-Vitro Diagnostic<br>Reagents, Calibrators and Controls used in<br>determination of Inflammatory Diseases<br>Markers, determination or monitoring of<br>Physiological Markers for a Specific Disease,<br>and the analysis of Haematology |

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REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE
I.3. Certificatul CE	Certificat CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Prodicatorul	Reprezentant	Ordin	Data	Cod vamal
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DM000147867	POMPĂ DE INFUZIE	Infusomat®	compact plus	8717050	Germania	B. BRAUN MELSUNGEN AG	TETIS INTERNATIONAL CO S.R.L.	A07.PS-01.Rg04-233	20-08-2018	
DM000088943	SERINGĂ CU POMPĂ DE INFUZIE	PERFUSOR®	COMPACT PLUS	8717030	Germania	B. BRAUN MELSUNGEN AG	TETIS INTERNATIONAL CO S.R.L.	A07.PS-01.Rg04-95	04-04-2018	

[Nr. catalog]\_Равно '8717030' ИЛИ [Nr. catalog]\_Равно '8717050'

ОЧИСТИТЬ