

P.05 Medical Devices - Audit
Certification Department



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, China

S. Liu
Email : mdsap@us.tuv.com

August 09, 2019

Re: Revised / replaced certificate
Requirement: ISO 13485:2016 under MDSAP
Certificate number: MD 457039 164153581-30

Dear Madame or Sir,

Enclosed please find the revised/replaced certificate with the above mentioned identification number, replacing the previous certificate MD 457039 164122201-70.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Song Liu 
Certification officer
P.05 Medical Devices - Audit

TUV Rheinland
of North America, Inc.

12 Commerce Road
Newtown, CT 06470
USA

Toll Free TUV-RHEINLAND
Tel 203-426-0888
Fax 203-426-4009
Web www.tuv.com
Mail info@us.tuv.com

Member of the
TÜV Rheinland Group

Certificate



Certificate No.: MD 457039 164153581-30

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, China

D-U-N-S No.: 54-534-2185

Certification criteria ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture, Distribution and Service of
Ultrasonic Diagnostic Systems and Medical Endoscope Systems

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 17063023 003

Issue Date: 2019-08-09

Effective Date: 2019-08-09

Expiry Date: 2021-07-26



A handwritten signature in blue ink, appearing to read "Songzi", written over a horizontal line.

Certification officer: S.Liu
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

Certificate



Certificate No.: MD 457039 164153581-30
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, China
Scope: The scope of Certification also includes the following additional site:

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, China

D-U-N-S No.: None

Scope: Manufacture and Service of Ultrasonic Diagnostic Systems
and Medical Endoscope Systems

SONOSCAPE MEDICAL CORP.
Room 201 & 1401, A4 Building, Nanshan Intelligence Park,
1001 Xueyuan Blvd, Taoyuan Subdistrict, Nanshan District,
Shenzhen, 518071, Guangdong, China

D-U-N-S No.: None

Scope: Design and Development of Ultrasonic Diagnostic Systems
and Medical Endoscope Systems

Project No.: 17063023 003
Issue Date: 2019-08-09
Effective Date: 2019-08-09
Expiry Date: 2021-07-26



A handwritten signature in blue ink that reads "S. Liu".

Certification officer: S.Liu
TUV Rheinland of North America, Inc.

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