

**Business Stream Products
Certification Department**



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

SONOSCAPE MEDICAL CORP.
Yuehai Subdistrict, Nanshan Distric
Shenzhen
518057 GUANGDONG
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date June 06, 2019

Application for : QMS

Certificate No. : SX 60138554 Sheet 0001

Device : Only for QM-System audit

Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60138554 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
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Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the 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
China

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-06-06
Certificate Registration No.: SX 60138554 0001
An audit was performed. Report No.: 17032653 018
This Certificate is valid until: 2022-04-22

Certification Body



Date 2019-06-06



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138554 0001
Report No.: 17032653 018

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
China

Scope: Design and development, Manufacture and Distribution of
Medical Endoscope System, Ultrasonic Diagnostic Systems,
Hematology Analyzers and Reagents;
Manufacture and Distribution of Electrocardiograph

Sites included:

Room 201 & 202, 12th Building, Shenzhen Software Park
Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict,
Nanshan District, Shenzhen, 518057, Guangdong, China

Distribution of Medical Endoscope System, Ultrasonic
Diagnostic Systems, Hematology Analyzers and Reagents;
Manufacture and Distribution of Electrocardiograph

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

Manufacture of Medical Endoscope System, Ultrasonic
Diagnostic Systems, Hematology Analyzers

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-06-06



S. Liu

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60138554 0001
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Room 201 & 202, 12th Building,
Shenzhen Software Park Phase II,
1 Keji Middle 2nd Road,
Yuehai Subdistrict, Nanshan District
Shenzhen
518057 Guangdong
China

Scope:

Sites included:

1/F(B), Building A3 in Xinjianxing Technical Industrial
Park, Fengxin Road, Loucun Community, Gongming
Subdistrict, Guangming New District, Shenzhen, China

Manufacture of Hematology Reagents

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

Design and development of Medical Endoscope System,
Ultrasonic Diagnostic Systems, Hematology Analyzers
and Reagents

Certification Body



Date: 2019-06-06

