

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
P.R. 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: 2020-05-17

Certificate Registration No.: SX 60149175 0001

An audit was performed. Report No.: 17032653 021

This Certificate is valid until: 2022-04-22

Certification Body



Date 2020-05-17



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

Doc. 1/2 Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60149175 0001
Report No.: 17032653 021

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, Ultrasonic Diagnostic Systems,
Hematology Analyzers and Reagents;

Sites included:
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, Hematology Analyzers and Reagents;

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, Hematology Analyzers

Certification Body



Date: 2020-05-17


Herbert Zhong



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60149175 0001
Report No.: 17032653 021

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:

Sites included:

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

Manufacture of Hematology Reagents

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

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

Certification Body



Date: 2020-05-17



Business Stream Products
Certification Department



TÜVRheinland®



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

SONOSCAPE MEDICAL CORP.
Yuehai Subdistrict, Nanshan District
Shenzhen
518057 GUANGDONG
P.R. CHINA

Contact

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

Date May 18, 2020

Application for : QMS
Certificate No. : SX 60149175 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 60149175 0001
replacing the previous certificate.

Kind regards

Certification body

Herbert Zhong

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

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