

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
SONOSCAPE MEDICAL CORP.
4/F, 5/F, 8/F, 9/F & 10/F
Yizhe Building
Yuquan Road, Nanshan
Shenzhen
518051 Guangdong
China

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

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2015-01-26
Certificate Registration No.: SX 60099458 0001
An audit was performed. Report No.: 17032653 003
This Certificate is valid until: 2018-01-25

Certification Body



Date 2015-01-26



S. Liu

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. 1/1, Rev. 0

Attachment to
Registration No.: SX 60099458 0001
Report No.: 17032653 003

Organization: SONOSCAPE MEDICAL CORP.
4/F, 5/F, 8/F, 9/F & 10/F
Yizhe Building
Yuquan Road, Nanshan
Shenzhen
518051 Guangdong
China

Scope: Design and development, Manufacture and Distribution of
Medical Endoscope Systems in the area of Gastroenterology,
Electrocardiograph, Ultrasonic Diagnostic Systems and
Hematology Analyzers and Reagents

Sites included:

4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building,
Yuquan Road, Nanshan, Shenzhen, 518051, China

Design and development, Manufacture and Distribution of
Medical Endoscope Systems in the area of Gastroenterology,
Electrocardiograph, Ultrasonic Diagnostic Systems and
Hematology Analyzers and Reagents

1/F(S) & 5/F, Nanfeng Building, Nanshan Yungu Innovation
Industrial Park, 1183 Liuxian Blvd., Taoyuan Subdistrict,
Nanshan, 518055, Shenzhen, China

Manufacture of Ultrasonic Diagnostic Systems

Certification Body



Date: 2015-01-26



S. Liu

Certificate



TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that

SONOSCAPE MEDICAL CORP.
4/F, 5/F, 8/F, 9/F & 10/F
Yizhe Building
Yuquan Road, Nanshan
518051 Shenzhen Guangdong
China

has established and maintained a
Quality Management System
according to
ISO 13485:2003

Audit Report No.:	17033101 003
Certificate Registration No.:	74 500 4638
Expiry Date:	September 10, 2016

for the Design and Development, Manufacture and
Distribution of Medical Endoscope Systems in the area of
Gastroenterology, Electrocardiograph, Ultrasonic Diagnostic
Systems and Hematology Analyzers and Reagents

(see attachment for additional sites covered by this
registration)



Certification Officer: S. Liu

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: January 26, 2015

Attachment

**Quality Management System
according to ISO 13485:2003**

for

SONOSCAPE MEDICAL CORP.
4/F, 5/F, 8/F, 9/F & 10/F
Yizhe Building
Yuquan Road, Nanshan
518051 Shenzhen Guangdong
China

The scope of the registration includes the following sites:

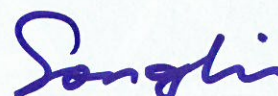
4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building,
Yuquan Road, Nanshan, Shenzhen, 518051, China

Design and development, Manufacture and Distribution of
Medical Endoscope Systems in the area of Gastroenterology,
Electrocardiograph, Ultrasonic Diagnostic Systems and
Hematology Analyzers and Reagents

1/F(S) & 5/F, Nanfeng Building, Nanshan Yungu Innovation
Industrial Park, 1183 Liuxian Blvd., Taoyuan Subdistrict,
Nanshan, 518055, Shenzhen, China

Manufacture of Ultrasonic Diagnostic Systems

Audit Report No.:	17033101 003
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Expiry Date:	September 10, 2016



Certification Officer: S. Liu

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: January 26, 2015

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