

**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](mailto:service@de.tuv.com)

Date June 06, 2019

**Application for : Vollst. QMS, Anhang II MDD**  
Certificate No. : HD 60138552 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the  
new certificate No. HD 60138552 0001  
replacing the previous certificate.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

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Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://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

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60138552 0001

**Report No.:** 17032653 018

**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

**Products:** Ultrasonic Diagnostic Systems, Medical Endoscope Systems  
(see attachment for additional sites included)

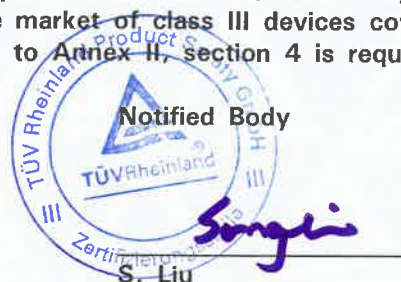
Replaces Approval, Registration No.: HD 60128046 0001

**Expiry Date:** 2023-06-18

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.

**Effective Date:** 2019-06-06

**Date:** 2019-06-06



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60138552 0001  
**Report No.:** 17032653 018

**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

**Sites included:**

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

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

**Date:** 2019-06-06



**S. Liu**

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518057 GUANGDONG  
CHINA

Contact

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Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date June 06, 2019

**Application for : QMS Produktion, Anhang V MDD**  
Certificate No. : DD 60138551 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the  
new certificate No. DD 60138551 0001  
replacing the previous certificate.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

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LGA Products GmbH

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Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60138551 0001

**Report No.:** 17032653 018

**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

**Products:** Digital Electrocardiograph

Replaces Approval, Registration No.: DD 60119845 0001

**Expiry Date:** 2022-08-20

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-06-06

**Date:** 2019-06-06



**Notified Body**

S. Liu

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