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 : **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

Digitally signed by Ermicev Alexandr
Date: 2022.01.28 16:02:04 EET
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

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

Notified Body

S. Liu

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

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

TÜV Rheinland Product Safety GmbH
TÜVRheinland
Zertifizierungsstelle

Notified Body

Date: 2019-06-06

S. Liu

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 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

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

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

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.