

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

**Registration No.:** HD 60128046 0001

**Report No.:** 17032653 014

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

**Products:** Ultrasonic Diagnostic Systems, Medical Endoscope Systems  
(see attachment for additional site included)  
Replaces Approval, Registration No.: HD 60106282 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:** 2018-06-19

**Date:** 2018-04-16



**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**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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Yuquan Road, Nanshan  
Shenzhen  
518051 Guangdong  
China

**Site 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

**Date:** 2018-04-16

**Notified Body**



S. Liu



**Business Stream Products**  
**Certification Department**



**TÜVRheinland®**

**LGA**

**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

**SONOSCAPE MEDICAL CORP.**  
4/F, 5/F, 8/F, 9/F & 10/F  
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518051 GUANGDONG  
CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date April 16, 2018

**Application for : Vollst. QMS, Anhang II MDD**  
Certificate No. : HD 60128046 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 60128046 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

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LGA Products GmbH

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90431 Nürnberg

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