

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

LGA Pr

TÜVRheinla

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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

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Report No.:

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SONOSCAPE MEDICAL CORP.

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Yizhe Building

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

