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

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-04-16

S. Liu