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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