EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 2027206-1
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 P.R. China
Products:	Ultrasonic Diagnostic Systems, Medical Endoscope Systems

Digitally signed by Lungu Ion
Date: 2023.04.02 13:37:46 GMT+03:00
Reason: MoldSign Signature
Location: Moldova

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.

Report No.:	10918672-100
Effective date:	2021-04-16
Expiry date:	2024-05-26
Issue date:	2021-04-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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Manufacturer: SONOSCAPE MEDICAL CORP.
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1 Keji Middle 2nd Road, Yuehai Subdistrict,
Nanshan District, Shenzhen
518057 Guangdong
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	SONOSCAPE MEDICAL CORP. 4/F(B), 1/F(S), 5/F, Nanfeng Building Nanshan Yungu Innovation Industrial Park, 4093 Liuxian Blvd., Taoyuan Subdistrict, Nanshan Shenzhen 518055 Guangdong P.R. China	Ultrasonic Diagnostic Systems, Medical Endoscope Systems
/02	SONOSCAPE MEDICAL CORP. Room 201 & 1401, A4 Building, Nanshan Intelligence Park, 1001 Xueyuan Blvd, Taoyuan Subdistrict, Nanshan District, Shenzhen, 518071 Guangdong P.R. China	Ultrasonic Diagnostic Systems, Medical Endoscope Systems

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