

# EC Certificate



**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



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



A handwritten signature in blue ink, appearing to read 'W. Hsu'.

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.

# EC Certificate

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The scope of certification includes the following manufacturing sites:

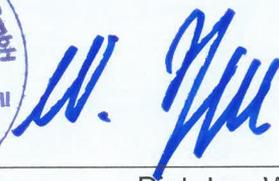
No.	Location	Product groups manufactured
/01	SONOSCAPE MEDICAL CORP. 4/F(B), 1/F(S), 5/F, Nanfeng Building Nanshan Yungu Innovation Industrial Park, 4093 Liuxian Blvd., Taoyuan Subdistrict, Nanshan Shenzhen 518055 Guangdong P.R. China	Ultrasonic Diagnostic Systems, Medical Endoscope Systems
/02	SONOSCAPE 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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TÜV Rheinland LGA Products GmbH • 51105 Köln

SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road,  
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Shenzhen  
518057 Guangdong  
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Contact

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Date August 11, 2022

**Application for: QMS**

Certificate No. : HD 2027206-1  
Requirement : Richtlinie 93/42/EWG  
Confirmation letter ID : 2021-04-16\_HD 2027206-1  
Report no. : 10920646-100

Dear Madame or Sir

**Update of information to Certificate no. HD 2027206-1, issued on 09.08.2022**

The change notification received on 08.04.2022 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Addition new address: SONOSCAPE MEDICAL CORP.  
SonoScape Medical Building, No.2 Road  
(West), Shuangming Blvd (South),  
Guangming High-tech Park (East),  
Guangming District, Shenzhen, 518107,  
Guangdong, P.R. China

TÜV Rheinland  
LGA Products GmbH

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Headquarter

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Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller

Best regards,

Dipl.-Ing. W. Hsu  
Certification body