

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


TÜVRheinland[®]

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



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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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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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,
Yuehai Subdistrict, Nanshan District,
Shenzhen
518057 Guangdong
P.R. China

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date August 11, 2022

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

Best regards,

Dipl.-Ing. W. Hsu
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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