

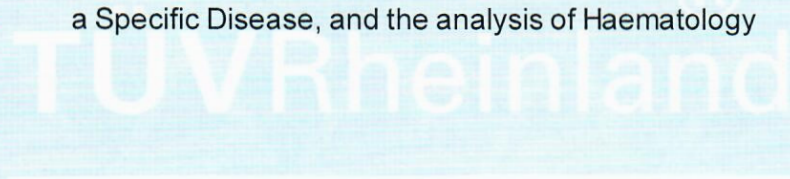
Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2027206-1

Organization: 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

Scope: Design and Development, Manufacture and Distribution of Medical Endoscope Systems, and Ultrasonic Diagnostic Systems;
Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Analysers, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Reagents, Calibrators and Controls used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10920646-100
Effective date: 2022-08-09
Expiry date: 2025-04-22
Issue date: 2022-08-09



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



Certificate



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EN ISO 13485:2016**

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Shenzhen
518057 Guangdong
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o 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	Distribution of Medical Endoscope Systems, Ultrasonic Diagnostic Systems; In-Vitro Diagnostic Analysers, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Reagents, Calibrators and Controls used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology
/02	c/o 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	Manufacture of Medical Endoscope Systems, Ultrasonic Diagnostic Systems; In-Vitro Diagnostic Analysers used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology

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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

The scope of certification also covers the following:

- | | | |
|-----|---|--|
| /03 | c/o SONOSCAPE MEDICAL CORP.
1/F(B) , Building A3 in Xinjianxing
Technical Industrial Park, Fengxin Road,
Loucun Community, Gongming
Subdistrict, Guangming New
District, Shenzhen,
518107 Guangdong
P.R. China | Manufacture of In-Vitro Diagnostic Test Kits,
In-Vitro Diagnostic Reagents, Calibrators and
Controls used in determination of
Inflammatory Diseases Markers,
determination or monitoring of Physiological
Markers for a Specific Disease, and the
analysis of Haematology |
| /04 | c/o SONOSCAPE MEDICAL CORP.
Room 201 & 1401,
A4 Building, Nanshan Intelligence Park,
1001 Xueyuan Blvd, Taoyuan Subdistrict,
Nanshan District, Shenzhen,
518071 Guangdong
P.R. China | Design and development of Medical
Endoscope Systems, Ultrasonic Diagnostic
Systems; In-Vitro Diagnostic Analysers, In-
Vitro Diagnostic Test Kits, In-Vitro Diagnostic
Reagents, Calibrators and Controls used in
determination of Inflammatory Diseases
Markers, determination or monitoring of
Physiological Markers for a Specific Disease,
and the analysis of Haematology |

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Dipl.-Ing. W. Hsu

TÜVRheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EN ISO 13485:2016

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Organization: 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

The scope of certification also covers the following:

/05	c/o 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	Manufacture of Medical Endoscope Systems, Ultrasonic Diagnostic Systems; In-Vitro Diagnostic Analysers used in determination of Inflammatory Diseases Markers, determination or monitoring of Physiological Markers for a Specific Disease, and the analysis of Haematology
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Yuehai Subdistrict, Nanshan District,
Shenzhen
518057 Guangdong
P.R. China

Application for: QMS

Certificate No.: SX 2027206-1

Requirement : EN ISO 13485:2016

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date August 10, 2022

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2027206-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Dipl.-Ing. W. Hsu
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller