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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 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

EUDAMED Single Registration No.: CN-MF-000009623

Products: Products of Class IIa:
Z110401 – ULTRASOUND SCANNERS
Z110402 – ULTRASOUND PROBES
Z120204 – INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Z120205 – UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120206 – LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120290 – VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY

Authorised representative(s): Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-10-14

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10918951-130

Effective date: 2022-10-14

Expiry date: 2027-07-29

Issue date: 2022-10-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TUVRheinland®

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

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

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

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

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

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

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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

Contact

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

Date August 10, 2022

Application for: QMS
Certificate No.: SX 2027206-1
Requirement : EN ISO 13485:2016

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

Tillystraße 2
90431 Nuremberg

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

EU DECLARATION OF CONFORMITY

The following EU declaration of conformity exemplifies the required content according to Regulation (EU) 2017/745.

EU DECLARATION OF CONFORMITY

Name and address of the 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
Single registration number (SRN)	CN-MF-000009623
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Single registration number (SRN)	DE-AR-000000001

We declare under our sole responsibility that

the medical device:	Video System Center (model No.: X-2600, X-2600S, X-2600A, X-2600B, X-2500, X-2500S, X-2500A, X-2500B, X-2400, X-2400S, X-2400A, X-2400B, X-2300, X-2300S, X-2300A, X-2300B)
of class:	IIa according to Rule 12 in annex VIII of Regulation (EU) 2017/745
Basic UDI-DI	69458686X-2600ME
EMDN code	Z120204

meets the provisions of the Regulation (EU) 2017/745.

Conformity assessment procedure:	**Regulation (EU) 2017/745 Annex IX Chapters I and III**
Registration No.:	**HZ 2027206-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, May 9, 2024
Place, date

Zhou Wenping Vice President
Name and function

EU DECLARATION OF CONFORMITY

The following EU declaration of conformity exemplifies the required content according to Regulation (EU) 2017/745.

EU DECLARATION OF CONFORMITY

Name and address of the 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
Single registration number (SRN)	CN-MF-000009623
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Single registration number (SRN)	DE-AR-000000001

We declare under our sole responsibility that

the medical device:	Video Gastroscope (model No.: EG-X20)
of class:	IIa according to Rule 5 in annex VIII of Regulation (EU) 2017/745
Basic UDI-DI	69458686EG-X20SJ
EMDN code	Z120205

meets the provisions of the Regulation (EU) 2017/745.

Conformity assessment procedure:	**Regulation (EU) 2017/745 Annex IX Chapters I and III**
Registration No.:	**HZ 2027206-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, May 9 , 2024
Place, date

Zhou Wenping Vice President
Name and function

EU DECLARATION OF CONFORMITY

The following EU declaration of conformity exemplifies the required content according to Regulation (EU) 2017/745.

EC DECLARATION OF CONFORMITY

Name and address of the 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
Single registration number (SRN)	CN-MF-000009623
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Single registration number (SRN)	DE-AR-000000001

We declare under our sole responsibility that

the medical device:	Video Colonoscope (model No.: EC-X20R, EC-X20RL)
of class:	IIa according to Rule 5 in annex VIII of Regulation (EU) 2017/745
Basic UDI-DI	69458686EC-X20RRY
EMDN code	Z120206

meets the provisions of the Regulation (EU) 2017/745.

Conformity assessment procedure:	**Regulation (EU) 2017/745 Annex IX Chapters I and III**
Registration No.:	**HZ 2027206-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, May 9, 2024

Place, date

Zhou Wenping Vice President

Name and function