Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. **242** din **10.11.2023**

"Health Medical Solutions" SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011, E-mail: info@hms.md, srl.hms.moldova@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor **clasa de risc IIa, annex IX of directive 93/42/EEC:**

Sistem de Videocolonoscopie - Sistem Video Colonoscopie HD-550, cu urmatoarele componente:

1. VIDEOPROCESOR, denumire comercială – **Sonoscape**, model – **HD-550**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine - **China**;

2. VIDEOCOLONOSCOP, denumire comercială – **Sonoscape**, model – **EC-500T**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine - **China**;

3. SURSĂ DE LUMINĂ, denumire comercială – **Sonoscape**, model – **VLS-55Q**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine – **China**.

Se anexează următoarele acte:

1. Împuternicirea de la Producator din **01.11.2023**;
2. Certificat CE nr. **HD 2027206-1 din 16.04.2021** (valabil pînă la 26.05.2024)
3. Declaratie de conformitate SONOSCAPE MEDICAL CORP. din 17.04.2021
4. Certificat ISO 13485:2016 No.**SX 2027206-1** din 23.04.2022 (valabil pînă la 22.04.2025);
5. Declaraţie pe proprie răspundere.

Data **10.11.2023**

Semnătura

Digitally signed by Lungu Ion
Date: 2023.11.11 17:48:43 GMT+02:00
Reason: MoldSign Signature
Location: Moldova

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE
Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

“Health Medical Solutions” SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011 E-mail: info@hms.md, srl.hms.moldova@gmail.com, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Sistem de Videocolonoscopie - Sistem Video Colonoscopie HD-550, cu urmatoarele componente:

1. VIDEOPROCESOR, denumire comercială – **Sonoscape**, model – **HD-550**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine - **China**;

2. VIDEOCOLONOSCOP, denumire comercială – **Sonoscape**, model – **EC-500T**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine - **China**;

3. SURSĂ DE LUMINĂ, denumire comercială – **Sonoscape**, model – **VLS-55Q**, producător – **SONOSCAPE MEDICAL CORP**., țara de origine – **China**.

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura*

_____

Lungu Ion, Administrator
+37379627404, +37369423432 Data 10.11.2023

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

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.

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

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

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.

EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

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
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

We declare under our sole responsibility that

the medical device:	HD-550 Video Endoscope System including (Product Name) Video Gastroscope: (model No.EG-550, EG-550L) Video Colonoscope: (model No.EC-550, EC-550T, EC-550L, EC-550L/T) Image Processor: (model No.HD-550Exp, HD-550, HD-550Pro, HD-550S, HD-510, HD-500Plus) Light Source: (model No.VLS-50T/VLS-50D, VLS-55Q/VLS-55T/VLS-51T/VLS-51D) (Model Designation)
of class:	IIa according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:	**Directive 93/42/EEC Annex II, excluding Section 4**
Registration No.:	**HD 2027206-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, April 17, 2021

Zhou Wenping Vice President

Place, date

Name and function

12th Building, Shenzhen Software Park Phase Ⅱ,1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District
Shenzhen
518057 Guangdong China
Tel: 86-755-26722890
Fax: 86-755-26722850
E-mail: sonoscape@sonoscape.net

SonoScape

Date: 1st Nov, 2023

LETTER OF AUTHORIZATION

To Whom it May Concern,

We, **SonoScape Medical Corp.,**, who are official manufacturer of ultrasound, Endoscopy systems , having headquarters at _12th Building, Shenzhen Software Park, 1 Keji Middle 2nd Road, Nanshan, Shenzhen, China, assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Republic of Moldova, Chișinău, MD-2019, 128, Grenoble str., OF.011.

- as authorized representative in the Republic of Moldova in correspondence with the conditions of Directive 93/42/EEC.
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the in territory of Republic of Moldova, and to perform Essential Duties required by Law No. 102 on 09.06.2017 regarding Medical Devices.

This Authorization letter is valid until 30th June, 2024. SonoScape Medical Corp., reserves all the rights.

SonoScape Medical Corp.
Deputy Sales Director: George Qing

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.:	10919683-100
Effective date:	2022-04-23
Expiry date:	2025-04-22
Issue date:	2022-04-14

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Jason Pan
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.: 10919683-100
Effective date: 2022-04-23
Expiry date: 2025-04-22
Issue date: 2022-04-14

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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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.: 10919683-100
Effective date: 2022-04-23
Expiry date: 2025-04-22
Issue date: 2022-04-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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D-ZM-14169-01-02