Chapter 9
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:	Digital Color Doppler Ultrasound System Model: E5 Exp/E5/E5 Pro/E3 Exp/E3/E3 Pro/E2 Exp/E2/ E2 Pro/E1 Exp/E1/E1 Pro (Supported Probes: 3C-A, L741, 6V1, 6V3, 3P-A, EC9-5, PWD2.0, 7P-B, C613, 12L-B, L746, C361, 2P1, 10I2, C322, C1-6, 9L-A, 18L-A, 13L-A, 10L-I, 6V7, 6V3A, VC6-2, C542, 6CT-A, BCC9-5, S1-5, CWD2.0, 12LI-A)
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 20, 2021

Zhou Wenping

Vice President

Place, date / Name and function

Chapter 9
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:	Digital Color Doppler Ultrasound System Model: P60 Exp/P60 Pro/P60/P60 CV/ P70T/P70S/P60S/P60 VO/ P55/P55 Elite/ P55S/P50T/P50 Elite/P50E/P40T/P40 Elite/P40E/ P30T/P30 Elite/P30E/P25S/P22S (Supported Probes: 3C-A, C1-6, C1-6A, C2-9, C613, C322, C3-10V, 6V3, 6V1, 6V7, 6V3A, EC9-5, 12L-A, L741, 12L-B, 9L-A, L3-9, 18L-A, 13L-A, S1-5, 4P-A, 3P-A, 7P-A, 7P-B, 8P1, MPTEE, MPTEE mini, VC2-9, VC6-2, VE9-5, BCC9-5, BCL10-5, 12LT-A, 12LI-A, 6CT-A, 6CI-A, 10I2, LAP7, CWD2.0, L742, L752, 2P1)
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, June 14, 2021

Zhou Wenping

Vice President

Place, date / Name and function

Chapter 9

EC DECLARATION OF CONFORMITY

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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, 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:	Portable Digital Color Doppler Ultrasound System Model: S9 Exp/S9 Pro/S9/S8 Exp/S7/SSI-980/S6s/S2s/S2 Exp (Supported Probes: C353, C344, 3C-A, C1-6, L742, L752, L741, 10L1, 18L-A, 12L-A, 9L-A, 12L-B, 8P1, 2P1, 2P2, 5P1, 5P2, 4P-A, S1-5, 7P-A, 7P-B, 6V1, 6V3, EC9-5, C613, C611, C542, VE9-5, VC6- 2, BCC9-5, BCL10-5, 10I2, 6V7, LAP7, MPTEE mini, MPTEE, CWD2.0, CWD5.0, 10L-I, 6CT-A, 12LT-A, 6CI-A, 12LI-A, 12C-ER, 13L-A, C322, 6V3A)
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 20, 2021 — Zhou Wenping, Vice President

Place, date — Name and function

Chapter 9
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:	Digital Color Doppler Ultrasound System Model: P10 Exp/P10/P10Pro/P11/M10/P9/P9 Pro/P9 Exp/P12/P16/P18/E30S/E40S (Supported Probes: L741, 10L-I, 9L-A, 18L-A, 12L-B, 10I2, 6CI-A, 12LI-A, 3C-A, C322, C613, BCC9-5, VC6-2, C1-6, C542, 6V1, 6V3A, 6V7, 6V3, EC9-5, 3P-A, 7P-B, S1-5, L746, C361, 2P1, L752, 8P1, C612, CWD5.0)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

Chapter 9
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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:	Digital Color Doppler Ultrasound System Model: P20/P20Pro/P15/P22/P25/P10 Plus (Supported Probes: 3C-A, C1-6, 13L-A, L742, L752, ML3-18, 3P-A, 10L- I, 10I2, 8P1, 6V3, 6V3A, EC9-5, 6V1, VC6-2, VE9-5, C322, C613, PWD2.0, CWD5.0, LAP7, 12LT-A, 12LI-A, 6CT-A, 6CI-A, BCC9-5, BCL10-5, 6V7, S1-5, L741, 7P-B, 12C-ER, MPTEE, MPTEE mini, 12L- A, 12L-B, 9L-A, 18L-A, VC2-9, C1-6A, 7P-A, 4P-A)
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 20, 2021

Zhou Wenping Vice President

Place, date

Name and function

Chapter 9
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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:	Digital Color Doppler Ultrasound System Model: P50 Exp/P50 Pro/P50S/P50/P47/P40 Pro/P40 Exp/P40S/P40/P37/P30 Pro/P30 Exp/P30S/P30/P27 (Supported Probes: 3C-A, C1-6, C1-6A, C2-9, L742, 12L-A, 12L-B, 13L- A, 9L-A, 18L-A, 10I2, 10L-I, 4P-A, S1-5, 7P-A, 8P1, VE9-5, VC6-2, VC2-9A, VC2-9, VL12-5, VE3-10, 6V3, C3-10V, 6V3A, 6V7, EC9-5, 12C-ER, 6V1, BCC9-5, BCL10-5, C322, C613, 12LT-A, 12LI-A, 6CT-A, 6CI-A, ML3-18, PWD2.0, CWD2.0, CWD5.0, CWD8.0, MPTEE, MPTEE mini, LAP7, L741, 7P-B, 3P-A)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

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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:	Portable Digital Color Doppler Ultrasound System Model: S8/S8 Pro/S6 Pro/S6/S6BW (Supported Probes: C362, C344, C542, VC6-2, L741, L742, L743, L752, 10L1, 6V1, 6V1A, 6V3, 2P1, 5P1, C311, C611, EC9-5, BCC9-5, BCL10-5, MPTEE, MPTEE mini, C322, LAP7, 10I2)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

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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:	Portable Digital Color Doppler Ultrasound System Model: S8N/S6N/S2N/S2/S2BW (Supported Probes: C344, C354, C362, C542, VC6-2, 6V1, 6V3, L741, L742, L743, 10L1, 10I2, 2P1, 5P1, C311, C611, 6V1A, EC9-5, C322)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

Chapter 9

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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:	Digital Color Doppler Ultrasound System Model: S11 Exp/S11 Pro/S11/S11 N/S11BW (Supported Probes: C362, C344, C354, C542, L741, L742, L743, L752, 6V1, 6V3, 6V1A, EC9-5, 2P1, 5P1, C311, C611, VC6-2, 10L1, 10I2, BCC9-5, BCL10-5, MPTEE, MPTEE mini, C322)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

Chapter 9

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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: Digital Color Doppler Ultrasound System
Model: S12 Exp/S12 Pro/S12/S11 Plus/M12/S10/S11s/S12s
(Supported Probes: C344, 3C-A,VC6-2, VE9-5, L741, L742, 10 L1, 2P1, 5P1, C322, C542, C611, C613, 6V1, 6V3, 6V7, EC9-5, 10I2, BCL10-5, BCC9-5, 6V3A, 6V1A, 3P-A, 7P-B, MPTEE, MPTEE mini)

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 20, 2021 — Zhou Wenping, Vice President

Place, date — Name and function

Chapter 9

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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:	Digital Color Doppler Ultrasound System Model: S20 Exp/S20 Pro/S20/S15 (Supported Probes: C362, C344, VC6-2, C542, L741, L742, L743, L752, 10L1, 6V1, 6V3, EC9-5, BCC9-5, BCL10-5, 2P1, 5P1, MPTEE, MPTEE mini, C611, C311, C322, 10I2, LAP7)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

Chapter 9

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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: Digital Color Doppler Ultrasound System
Model: S22 Exp/S22 Pro/S22/S20 Plus/M22
(Supported Probes: C322, C344, C353, C354, C542, C611, C613, VC6-2, 3C-A, 4P-A, 6V7, 10L-I, 6V2A, L741, L742, L752, 10L1, 10I2, 6V1, 6V1A, 6V3, EC9-5, BCC9-5, BCL10-5, 2P1, 5P1, MPTEE, MPTEE mini, LAP7, CWD2.0, CWD5.0, PWD2.0, 3P-A, 7P-B, 18L-A, 6CT-A, 12LT-A, 6CI-A, 12LI-A, 12C-ER, 9L-A, 6V-A, 13L-A, 3C-B, 4P-B, 12P-B, 8V-A)

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 20, 2021

Zhou Wenping Vice President

Place, date

Name and function

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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:	Digital Color Doppler Ultrasound System Model: S50 Exp/S50/S50 Pro/S40 Plus/S-Maso/S50 CV/S50 VO (Supported Probes: 3C-A, C542, L742, L743, L752, 4P-A, 5P2, 8P1, 6V1, 6V3, EC9-5, VC6-2, VL12-5, VE9-5, C322, C1-6, S1-5, 12L-A, 7P-A, C613, 10I2, 6V1A, 6V7, LAP7, MPTEE, MPTEE mini, PWD2.0, CWD2.0, BCC9-5, BCL10-5, CWD5.0, CWD8.0, C1-6A, C2-9, 12L-B, 13L-A, 9L-A, 18L-A, 10L-I, ML3-18, VC2-9A, VC2-9, VE3-10, C3-10V, 6V3A, 12C-ER, 12LT-A, 12LI-A, 6CT-A, 6CI-A, L741, 3P-A)
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 20, 2021

Zhou Wenping

Vice President

Place, date

Name and function

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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:	Digital Color Doppler Ultrasound System Model: S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci /S60 Elite/S-Light (Supported Probes: 3C-A, C1-6, C1-6A, C2-9, C322, C613, 13L-A, 12L-A, 12L-B, 18L-A, 9L-A, 4P-A, S1-5, 7P-A, VC2-9, VE9-5, 6V3, C3-10V, BCC9-5, BCL10-5, 6V7, 10I2, 12LT-A, 12LI-A, 6CT-A, 6CI-A, 6V3A, CWD2.0, 3P-A, 7P-B, 6V1, L3-9, MPTEE, MPTEE mini, LAP7, L741, L742, 8P1, VC6-2)
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 60138552 0001**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, April 20, 2021

Zhou Wenping

Vice President

Place, date / Name and function

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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:	Digital Color Doppler Ultrasound System Model: S60 Exp/S60/S60 Pro/S60 VO/S60 Maso/S59/S70N/ S50S/S50 Plus/S50 Elite/S55 (Supported Probes: 3C-A, C1-6, C1-6A, C2-9, C322, C613, 13L-A, 12L-A, 12L-B, 18L-A, 9L-A, 4P-A, S1-5, 7P-A, VC2-9, VE9-5, 6V3, C3-10V, BCC9-5, BCL10-5, 6V7, 10I2, 12LT-A, 12LI-A, 6CT-A, 6CI-A, 6V3A, CWD2.0, 3P-A, 7P-B, 6V1, L3-9, MPTEE, MPTEE mini, LAP7, L741, L742, 8P1, VC6-2.)
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 20, 2021

Zhou Wenping

Vice President

Place, date / Name and function

Chapter 9
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:	Digital Color Doppler Ultrasound System Model: S70 Exp/S70/S70 Pro/S70S/S70 VO/S60S/S60N (Supported Probes: 3C-A, C1-6, C1-6A, C2-9, C322, C613, 13L-A, 12L-A, 12L-B, 18L-A, 9L-A, 4P-A, S1-5, 7P-A, VC2-9, VE9-5, 6V3, C3-10V, BCC9-5, BCL10-5, 6V7, 10I2, 12LT-A, 12LI-A, 6CT-A, 6CI-A, 6V3A, CWD2.0, 3P-A, 7P-B, 6V1, L3-9, MPTEE, MPTEE mini, LAP7, L741, L742, 8P1, VC6-2)
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.

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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:	Digital Color Doppler Ultrasound System Model: SSI-5000/SSI-4000/SSI-2000/SSI-1500 (Supported Probes: C344, C542, C362, VC6-2, L741, L742, L743, L752, 10L1, 2P1, 5P1, C611, 6V1, 6V3, EC9-5, BCC9-5, BCL10-5, C322, 10I2, MPTEE, MPTEE mini)
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.

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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:	Digital Color Doppler Ultrasound System Model: SSI-5000N/SSI-4000N/SSI-3000N/SSI-2000N/SSI-1500N (Supported Probes: C344, C354, C362, VC6-2, 6V1, 6V3, L741, L742, L743, 10L1, 10I2, 2P1, 5P1, C311, C611, 6V1A, EC9-5)
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.

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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:	Digital Color Doppler Ultrasound System Model: SSI-6000/SSI-5800/SSI-5500/SSI-5500BW (Supported Probes: C344, C542, C362, VC6-2, L741, L742, L743, L752, 10L1, 2P1, 5P1, C611, 6V1, 6V3, EC9-5, BCC9-5, BCL10-5, C322, 10I2, MPTEE, MPTEE mini, LAP7)
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.

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Shenzhen, April 20, 2021

Zhou Wenping

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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:	Mobile Digital Color Doppler Ultrasound System Model: SSI-8000 Exp/SSI-8000 Pro/SSI-8000/SSI-8000 PE (Supported Probes: C344, C542, C362, VC6-2, L741, L742, L743, L752, 10L1, 2P1, 5P1, C611, 6V1, 6V3, EC9-5, BCC9-5, BCL10-5, C322, 10I2, MPTEE, MPTEE mini, LAP7)
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.

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Shenzhen, April 20, 2021

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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:	Digital Color Doppler Ultrasound System Model: X3 Exp/X3/X3 Pro/X3 Plus/X2 Plus/X1 Exp/X1/X1 Pro (Supported Probes: 3C-A, L741, 6V1, 3P-A, EC9-5, PWD2.0, 7P-B, C613, 10L-I, 9L-A, 12L-B, 13L-A, 18L-A, 10I2, 6CI-A, 6CT-A, 12LI-A, 12LT-A, C322, BCC9-5, BCL10-5, VC6-2, C1-6, C542, 6V3A, 6V7, 6V3, S1-5, CWD2.0, MPTEE, MPTEE mini, LAP7, L746, C361, C351, 2P1, L742)
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.

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Shenzhen, April 20,2021

Zhou Wenping

Vice President

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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:	Digital Color Doppler Ultrasound System Model: X5 Exp/X5/X5 Pro/X6 Exp/X6/X6 Pro (Supported Probes: 3C-A, C613, 6V1, L741, 3P-A, 7P-B, EC9-5, PWD2.0, 10L-I, 9L-A, 12L-B, 13L-A, 18L-A, 10I2, 6CI-A，6CT-A，12LI-A, 12LT-A，C322，BCC9-5, BCL10-5, VC6-2, C1-6, C542, 6V3A, 6V7, 6V3, S1-5, CWD2.0, MPTEE, MPTEE mini, LAP7, L746, C361, C351, 2P1, L742)
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.

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Shenzhen, April 20, 2021 — Zhou Wenping Vice President

Place, date — Name and function