Chapter 9

EC DECLARATION OF CONFORMITY

,

Digitally signed by Bolea Petru
Date: 2023.01.09 09:28:03 EET
Reason: MoldSign Signature
Location: Moldova

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: P25 Exp/P25 Elite/P20 Exp/P20 Elite/P22 Elite/P22 Exp/P15 Exp/P15 Elite (Supported Probes: L741,10L-I,9L-A,12L-B,10I2,6CI-A,6CT-A,12LI-A,12LT-A,3C-A,C322,C613,BCC9-5,BCL10-5,VC6-2, C1-6,6V1,6V3A,6V7,6V3,EC9-5,3P-A,S1-5,LAP7,MPTEE, MPTEE mini,L742,2P1,CWD2.0,C1-5,C1-6A,C2-9,6V1A,12L-A,L752,4P-A,7P-A,8P1,VE9-5
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.

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, Feb 21, 2022

Zhou Wenping

Vice President

Place, date / Name and function