
Chapter 9

EC DECLARATION OF CONFORMITY

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

Doc: 906-00107 rev.: A10 date: 2021-4-20

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.

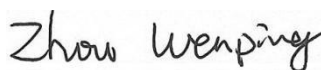
Conformity assessment procedure: **Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.: **HD 2027206-1**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Shenzhen, April 20, 2021

Place, date



Vice President

Name and function