Chapter 9

EC DECLARATION OF CONFORMITY

Digitally signed by Bolea Petru
Date: 2023.06.01 17:04:13 EEST
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, 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