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. 4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China
Name and address of the European Representative	SonoScape Europe S.r.l. Via Luigino Tandura, 74-00128 Rome, Italy

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, C351, C361, 2P1, 10I2, 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 60128046 0001**

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

Shenzhen, May 31, 2018

Wanping Zhou

Vice President

Place, date / Name and function