
Chapter 9

EC DECLARATION OF CONFORMITY

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

Doc:906-00224 rev.:A03 date:2018-05-31

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.

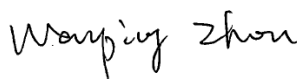
Conformity assessment procedure: / **Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.: **HD 60128046 0001**

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

Shenzhen, May 31, 2018

Place, date /



Vice President

Name and function