
Chapter 9

EC DECLARATION OF CONFORMITY

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

Doc: 906-01682 rev.: A01 date: 2022-2-25

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
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Name and address of the European Representative

We declare under our sole responsibility that

the medical device:

Digital Color Doppler Ultrasound System
Model: P12 Exp/P12 Elite/P12 Pro/R12/P12N/P11 Exp/P11 Elite/P11 Pro/R11/P11N/P10 Elite/P10N/R10/P9 Elite/M11/R9
(Supported Probes: 6V3,12LT-A,BCC9-5,10I2,10L1,10L-I,12LI-A,2P1,6CI-A,6CT-A,6V1,6V3A,6V7,C322,C361,C613,EC9-5,L741,L742,L752,12L-B,3C-A,3P-A,7P-A,9L-A,S1-5,C1-5,VE9-5,VC6-2, CWD5.0)

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 25, 2022

Place, date /



Vice President

Name and function