



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 764-5-2013

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor
FUJIFILM SONOSITE,INC.
21919 30th Dr SE
BOTHELL WA USA 98021

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Ann M. Ferriter
Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 6 day of May month 2013.

CATHRYN N MORRIS
Notary Public-Maryland
Montgomery County
My Commission Expires
January 04, 2017





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer/Distributor

FUJIFILM SONOSITE, INC.
21919 30th Dr SE
BOTHELL, WA, USA 98021

Name of Product(s)

SonoHeart® Hand Carried Echocardiography System and Accessories
SonoHeart® ELITE Hand Carried Echocardiography System and Accessories
SonoHeart® PLUS Hand Carried Echocardiography System and Accessories
SonoSite® 180 Hand Carried Ultrasound System and Accessories
SonoSite® 180PLUS Hand Carried Ultrasound System and Accessories
Battery
Carry Cases
CRT Stand
ECG Cable Assembly
L25 18 Gauge Needle Guide/Cover Kit
L25 21 Gauge Needle Guide/Cover Kit
L25 22 Gauge Needle Guide/Cover Kit
L25 Needle Guide Bracket
Power Supply
SiteCharge® Dual Battery Charger
SiteLink™ Image Manager
SiteLink™ Image Manager with DICOM
SiteStand® - Mobile Docking Station
SonoCalc® IMT
Transducer, C15/4-2 MHz
Transducer, C60/5-2 MHz
Transducer, C11/7-4 MHz
Transducer, ICT/7-4 MHz
Transducer, C8/8-5 MHz
Transducer, HST/10-5 MHz
Transducer, L25/10-5 MHz
Transducer, L38/10-5 MHz
Transducer, L52/10-5 MHz

-----END OF PRODUCT LIST-----

