



Certificate No. 512-1-2014

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
See Attached List (One Page)	Name of Manufacturer Legal Manufacturer 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.



Leila M. Lawrence

Leila M. Lawrence
Chief, Export Branch
Division of International Compliance 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 4 day of Feb month 2014.

Cathryn N. Morris

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





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Name of Manufacturer

Legal Manufacturer

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

Name of Product(s)

ULTRASOUND SYSTEM

SonoSite Edge™ Ultrasound System

TRANSDUCERS

Transducer, C8x/8-5 MHz

Transducer, C11x/8-5 MHz

Transducer, C60x/5-2 MHz

Transducer, D2x/2 MHz

Transducer, HFL38x/13-6 MHz

Transducer, HFL50x/15-6 MHz

Transducer, ICTx/8-5 MHz

Transducer, L25x/13-6 MHz

Transducer, L38x/10-5 MHz

Transducer, L38xi/10-5 MHz

Transducer, L52x/10-5 MHz

Transducer, P10x/8-4 MHz

Transducer, P11x/10-5 MHz

Transducer, P21x/5-1 MHz

Transducer, SLAx/13-6 MHz

Transducer, TEEEx/8-3 MHz

ACCESSORIES

Battery

Biopsy Guide Starter Kit, C8 Series

Biopsy Guide Starter Kit, C60 Series

Biopsy Guide Starter Kit, ICT Series

Biopsy Guide Starter Kit, L38 Series & HFL38 Series

Biopsy Guide Starter Kit, P10 Series

Biopsy Guide Starter Kit, P21 Series

Biopsy Guide Starter Kit, HFL50 Series

L25x 18 Gauge Needle Guide/Cover Kit

L25x 21 Gauge Needle Guide/Cover Kit

L25x 22 Gauge Needle Guide/Cover Kit

Edge/H-Universal™ Stand

Kit, Bar Code Scanner

Mini-Dock

Mouse, Optical

Carrying Cases

ECG Cable Assembly

PowerPark

PowerPack

Power Cord

Power Supply / Battery Charger

Printer/Video/ Audio Connecting Cables

Protective Connector Box

SiteLink™ Image Manager

SonoCalc® IMT

SonoSite® Workflow Solutions

Triple Transducer Connect Module

Wireless IEEE 802.11 b/g Option

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

