



Certificate No. 1213-2-2014

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:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

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
Chief, Export Branch
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from March 10, 2014 to March 09, 2016.





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

Name of Manufacturer

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21919 30th Dr SE
BOTHELL, WA USA 98021

Name of Product(s)

ULTRASOUND SYSTEM
X-Porte Ultrasound System
TRANSDUCERS
Transducer, C60xp/5-2 MHz
Transducer, HFL50xp/15-6 MHz
Transducer, ICTxp/9-5 MHz
Transducer, L25xp/13-6 MHz
Transducer, L38xp/10-5 MHz
Transducer, P21xp/5-1 MHz
ACCESSORIES
AC Cable, SPMU-to-Printer
AC Power Supply, X-Porte
Bar Code Scanner (USB)
Basket, Stand
Battery (set of 3)
Black and White Video Printer
Cable Assembly, Dock-to-Printer (USB)
Cable Assembly, HDMI, Dock-to-Clinical Monitor
Cable, AC Power, Extension
Carrying Cases
Display, Clinical Monitor, LED Backlight
Dual Foot Switch, USB
ECG Cable Assembly and Module
ECG Lead Wires (3-Lead)
Isolation Transformer
L25xp 18 Gauge Needle Guide/Cover Kit
L25xp 21 Gauge Needle Guide/Cover Kit
L25xp 22 Gauge Needle Guide/Cover Kit
L25xp Needle Guide Bracket
Mouse, Optical
Needle Guide Starter Kit, C60xp
Needle Guide Starter Kit, ICTxp
Needle Guide Starter Kit, L38xp
Needle Guide Starter Kit, P21xp
OB Custom Table Editor
Pedestal Mount, X-Porte Monitor, VESA
Power Supply, X-Porte, Clinical Monitor
PowerPark Dock/Stand Modules
Printer Bracket
Triple Transducer Connect
X-Porte Control Panel Assembly
X-Porte Dock w/ DVR (Digital Video Recorder)

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

