

# **FURLS Device Registration & Listing Initial Registration**

U.S. Food and Drug Administration  
Center for Devices and Radiological Health

Division of Industry and Consumer Education (DICE)

## **Instructions for Foreign, First Registration in Account**

This tutorial should only be used when 1) registering a facility that is located outside of the U.S.; 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN); and, 3) the owner/operator has no other registered facilities.

Step 1: Click <https://www.access.fda.gov/oa/> to open the FDA Industry Systems Website.

If you have created an account prior to starting this tutorial, enter the account ID and password, click "I Understand" and then click on the Login button.

If you have not yet created an account, click on "Create New Account" and follow the prompts until you get to the Account Management page.

Proceed to Step 2.

The screenshot displays the FDA Industry Systems website interface. At the top, the U.S. Department of Health and Human Services logo is visible. Below it, the FDA and OAA logos are shown alongside the text "ONLINE ACCOUNT ADMINISTRATION (OAA)". The main heading is "FDA Industry Systems".

The "Login" section includes a form with fields for "Account ID" and "Password". A checkbox labeled "I understand." is present, along with a "Login" button and a "Forgot your password" link. A "New User" section features a "Create New Account" button, with links for "See Instructions", "See Tutorials", and "Help Desk".

Two callout boxes provide instructions: one for existing users to enter account ID and password, and another for new users to click "Create New Account". A red warning message is also visible, stating: "WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals..."

At the bottom, the FDA logo is on the left, and navigation links for "Accessibility", "Browser Requirements", "FAQ", "Help Desk", and "Privacy" are on the right.

Step 2: Click "Device Registration & Listing" to begin the registration.

Proceed to Step 3.

**Note:** If you have only created an owner/operator account, the same contact information will appear on the registration record for both the owner/operator and official correspondent. If a different person is acting as official correspondent, you must create a sub account for that person before beginning the registration process.

## Account Management



Account Management

Edit Account Profile

Change My Password

Update System Access

Create a Subaccount

Deactivate a Subaccount

Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **san1169** for **SANCO**.

You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

CDRH - Center for Device and Radiological Health

Click to launch the Application(s)

Device Registration and Listing Module

Laboratory Developed Test Notification

CDRH Export Certification Application and Tracking System

Wed Aug 05 09:05:04 EDT 2015

Step 3: Review "Important Messages" and click "Continue" to proceed to the DRLM Main Menu. Proceed to Step 4.

Note: You must pay the fee to receive your Payment Identification Number (PIN) & Payment Confirmation Number (PCN) before you can register your facility.



### IMPORTANT MESSAGES

**NEW: The CDRH Learn Device Establishment Registration and Listing Course has been updated with the current registration and listing requirements. Please visit this website <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm> to view the course.**

The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. MDUFA III mandates that, beginning in Fiscal Year 2013, an annual registration user fee be paid for all types of establishments.

The fee for FY 2014 is \$3,313. There is no reduction in this fee for small businesses or any other groups. For more information about User Fees and MDUFA III see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAll/default.htm>

You must pay the fee before registering a new establishment or updating your existing registration(s) and/or listing(s) for FY 2014. If you have not paid the fee, please [visit this website](#). For assistance with paying the fee, please send an email to [userfees@fda.gov](mailto:userfees@fda.gov).

FDA primarily communicates with facilities via email. Verify that we have the correct email address at the top of this page. Then click the "Verify" button on our screen.

Click on this link if you need to pay the fee to get your PIN and PCN. Clicking the link will log you out of FURLS. After you get your PIN and PCN, you will need to log back into FURLS to register the facility.

If you are registering or re-registering a facility, click the "Pay User Fee" button below to proceed to the payment screen.

Please note a new feature has been added: You can now download all of your up-to-date listing information in Excel format. Just click "Download Your Listing Information", which is the third choice on the DRLM Main Menu.

> CONTINUE

Step 4: Review the "Important Notice" at the top of the DRLM Main Menu screen. Click on "Register a New Medical Device Facility". Proceed to Step 5.

**DRLM Main Menu**

Get Help ?

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

**Who Must Pay:** All establishments must pay the annual registration fee prior to registering or re-registering.

- [Annual Registration](#)  
*(Annual Review of Device Registration and Listing Information)*
- [View Your Registration and Listing Information](#)
- [Download Your Listing Information](#)
- [Change Registration Information for a Facility](#)
- [Cancel, Deactivate, or Reactivate a Facility Registration](#)
- [Change the Official Correspondent for a Facility](#)
- [Register a New Medical Device Facility](#)**
- [Transfer Ownership of a Facility \(Report Purchase\)](#)
- [Create Listings for Medical Devices](#)
- [Change, Deactivate, or Reactivate Listings](#)
- [Add/Replace Proprietary Names or Importers to Listings](#)

Step 5: If the **facility was previously registered**, enter the Registration Number or Owner/Operator Number and click "Search." If the **facility has not been registered**, leave the search fields empty and click "No Existing Registration or OO Number" and follow the prompts to register. Proceed to Step 6.

**DRLM**  
Device Registration & Listing Module

FDA FURLS HOME  
DRLM HOME

Register Your Facility  
**Register a New Facility** [Get Help ?](#)

If you already have a Registration Number or Owner Operator Number, enter it in the field below and click Search.  
If you do not have a Registration Number or Owner Operator Number, leave the field empty and click "No Existing Registration or OO Number".

Enter Registration Number or Owner Operator Number if previously registered. Then click "Search."

Registration Number  OR Owner Operator Number

If an establishment at this address has previously been registered with FDA as a device facility, but you do not know your Registration Number or Owner Operator Number, please see [regist@cdrh.fda.gov](mailto:regist@cdrh.fda.gov) for assistance. Do not create a new registration if a me... been registered at your address.

Click here if your facility has never been registered.

< CANCEL - RETURN to MAIN MENU   > SEARCH   > NO EXISTING REGISTRATION OR OO NUMBER

Step 6: The Registration Requirements page provides links to pay the annual registration user fee, to determine if your product is exempt, to get your FDA product codes, and to register your facility. If you have both your PIN and PCN, and have determined your device listing information, including the facility activities, click "Register My Facility". Proceed to Step 7.

# DRLM

Device Registration & Listing Module



## Register Your Facility Registration Requirements

**If you have not paid the annual registration user fee, and you do not have a PIN & PCN, click "FDA User Fee website" to pay the annual registration user fee.**

**Important Notice:** If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

**Who Must Pay:** All establishments must pay the annual registration fee prior to registering or re-registering.

On the next few pages, you will need to enter the business name and address of your medical device facility. If your facility is located outside of the United States, you will need to create a listing for each product that you import. With the exception of initial importers of products, you will need to create a listing for each product that you import. Facilities that only act as initial importers of products do not need to create a listing for each product that you import at your facility.

**To determine if your product is exempt, click "premarket notification & approval."**

**If you need the 3 letter FDA product code, click "product code(s)."**

[premarket notification and approval](#)

[product code\(s\)](#)

**To see a list of facility activities and their definitions, click "activities".**

[activities](#)


**Click here if you have paid the annual registration user fee and have your PIN & PCN.**

[> REGISTER MY FACILITY](#)

Step 7: On the Transfer of Ownership page, select "Yes" or "No" to indicate if the registration is for a facility that you have acquired that is already registered by another company. Then click "Continue Registration". Proceed to Step 8.

If you select "**Yes**" the system will take you through the Transfer of Ownership process. Follow the prompts through the transfer process. If you need assistance, contact [reglist@CDRH.FDA.GOV](mailto:reglist@CDRH.FDA.GOV).

**DRLM**  
Device Registration & Listing Module

 **FDA** FURLS HOME  
DRLM HOME

Register Your Facility  
**Transfer Of Ownership?** [Get Help ?](#)

Is this registration the result of buying a registered facility from another company or merging with another company at this location?

YES  NO

[< BACK](#) [< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE REGISTRATION](#)



**Step 8: The Owner/Operator and Official Correspondent Information page displays contact information for both owner/operator and official correspondent. Review for accuracy and then click “Continue Registration.” Proceed to Step 9A.**

**Edit:** Edit the information on this form by clicking “Return to Account Management.” When you have completed your edits, return to Step 2.

**Subaccounts:** If there are no subaccounts, the owner/operator contact person’s information will display for both the owner/operator and the official correspondent . If you created sub-accounts, the names associated with the sub-accounts will appear in the dropdown menu along with the owner operator contact person. You can choose any of these people to act as the official correspondent.

**Register Your Facility** Get Help ?

### Owner/Operator and Official Correspondent Information

The [Owner/Operator and Official Correspondent](#) information that you entered when you created or updated your FURLS account is displayed below. To make changes to either the Owner/Operator or the Official Correspondent information, you will need to exit the DRLM section of FURLS and [return to Account Management](#).

**Owner/Operator Information**

Contact Name:	Steven Nagy
Company:	SANCO
Address:	12345 Rockville Pike Rockville, MARYLAND, 20
Telephone:	301-7967814
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

**Official Correspondent Information**

	Istvan Nagy ▼
Contact Name:	Istvan Nagy
Company:	SANCO
Address:	12345 Rockville Pike, Rockville, MARYLAND, 20852, UNITED STATES
Telephone:	301-7967814
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

**Callout Boxes:**

- If there is at least one subaccount, a dropdown menu displays your choices for official correspondent.** (Points to the dropdown menu in the Official Correspondent Information section)
- If information is accurate, click “Continue Registration.”** (Points to the > CONTINUE REGISTRATION button)
- Edit this information by clicking “Return to Account Management.”** (Points to the < RETURN to ACCOUNT MANAGEMENT button)

**Buttons:**

- < CANCEL - RETURN to MAIN MENU
- > CONTINUE REGISTRATION
- < RETURN to ACCOUNT MANAGEMENT

Step 9A: On the Location Information page, enter the facility's physical address. If the facility's information matches that of either the owner/operator or official correspondent, click on the radio button next to owner/operator or official correspondent to autofill the location. You must also add any other business trade names for the facility. If known, you may also enter the facility DUNS number, facility URL. Then, click "Continue Registration." Proceed to Step 9B.

**Register Your Facility**  
**Location Information**

Fields marked with an asterisk (\*) are required.

**Establishment Information**  Same as Owner/Operator  Same as Official Correspondent

Choose Country/Area where Facility is Located:\* CHINA

Facility Name:\* SANCO Asia

Address Line 1:\* 12345 SANCO way

Address Line 2:

Postal Code:\* 11223

City:\* Dongguan City

Foreign State:\* Guangdong  
[Choose a Province / Territory](#)

Phone: Country Code: 86 Area/City Code: 12 Phone Number: 34567891 Extension:

Fax: Country Code: 86 Area/City Code: 12 Fax Number: 34567892

DUNS Number: (Enter only the 9-digit number, no dashes or other characters)

Click box if this establishment is located in a foreign trade zone:

Facility URL:

Other Business Trade Name(s):  [remove](#)

[Add More Trade Names:](#)

[CLEAR](#) [BACK](#) [CONTINUE REGISTRATION](#)

Click "Same as Owner/Operator" or "Same as Official Correspondent" to autofill the facility's address section.

If unable to use the autofill function, enter address by typing directly into the text boxes.

If known, provide the facility DUNS number and URL.

Other business trade names for the facility must be added in this section.

After you have provided as much facility information as possible, click on "Continue Registration".

Step 9B: On the U.S. Agent Information page, enter the name, physical address, phone number, and email address of the facility's U.S. Agent. The U.S. Agent must be located in the United States. The responsibilities of a U.S. Agent can be viewed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm> After you have entered the U.S. Agent information, click on "Continue". Proceed to Step 10A.

Register Your Facility  
**U.S. Agent Information**

**FACILITY:** SANCO ASIA, DONGGU

United States Agent Information  Same as Owner/Operator  Same as Official Correspondent

Fields marked with an asterisk (\*) are required.

Contact Name:\* Istvan Nagy  
Contact Title: Mr  
Business Name: SANCO  
Address Line 1:\* 12345 Rockville Pike  
Address Line 2:  
Zip Code:\* 20852  
City:\* Rockville  
State:\* Maryland

Phone:\*  
Area/City Code: 301 Phone Number: 7967814 Exten:  
Fax:  
Area/City Code: Fax Number:

DUNS Number:  
(Enter only the 9-digit number, no dashes or other characters)

E-mail: steve.nagy@fda.hhs.gov

< CLEAR < BACK > CONTINUE

Click "Same as Owner/Operator" or "Same as Official Correspondent" to autofill the U.S. Agent's address section, if it is the same person.

If the U.S. agent is neither the official correspondent nor the owner operator, enter address and phone number by typing directly into the text boxes.

After you have entered the U.S. Agent information, click on "Continue".

Step 10A: On the Identify Facility's Products page, click "Add New Product". Proceed to Step 10B.

Register Your Facility

## Identify Facility's Products

Get Help ?

**FACILITY:** *SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA*

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

No Listings have been entered previously for your company. Select ADD NEW PRODUCT to Continue.

< BACK

< CANCEL - RETURN TO MAIN MENU

> ADD NEW PRODUCT

Step 10B: On the Enter Premarket Submission Number page, if the device is not exempt, enter the premarket submission number, and click "Continue." Proceed to Step 11.

If the device is exempt, click "Continue." Proceed to Step 10C.

If the device **is part of a combination product that includes a drug or biologic**, click the box (indicated below).

Register Your Facility  
**Enter Premarket Submission Number** Get Help ?

**FACILITY:** *SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA*

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- De Novo (DEN) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you believe the product you are listing falls under enforcement discretion, preamendment or import for export, please contact the CDRH Registration and Listing Helpdesk at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

If your device is exempt from FDA premarket notification requirements, leave the box empty.

If the product is a combination product, please check the Combination Product checkbox and then click "Continue".

Enter the Premarket Submission Number:

Click this box if your device is part of a combination product that includes a drug or biologic

If your device is part of a combination product that includes a drug or biologic, click here. You can view information about combination products at <http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm>

Step 10C: On the Dental Laboratory Question page, preview the question and click "Yes" or "No." Click "Continue" to proceed to Step 10D.

Create a New Medical Device Listing Get Help ?

### Dental Laboratory Question

**SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA**

Is this a product exported to the United States from a dental laboratory located outside of the United States?

YES     NO

Step 10D: If the device is exempt, enter the 3 letter FDA product code or word(s) that describe the device in the “Enter the Product Code or a word or words describing the device” text box on the View Listing Product Codes page. Click “Filter” to display a list of products. Proceed to Step 10E.

Register Your Facility Get Help ?

## View Listing Product Codes

**FACILITY:** SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

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	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input type="radio"/>	CLINICAL CHEMISTRY	CKH	Acid phosphatase, beta glycerophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CKE	Acid phosphatase, thymolphthale inmonophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CKB	Acid phosphatase, naphthyl phosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CJR	Acid phosph		ion
<input type="radio"/>	CLINICAL CHEMISTRY	CJN	Acid phosph		ion
<input type="radio"/>	CLINICAL CHEMISTRY	JFH	Acid phosph		ion

Please make a selection or selections below that most closely describe your combination product:

- CONVENIENCE KIT OR CO-PACKAGE
- PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE,PATCH,ETC.)
- DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG

You will only see this area if you checked the combination product box in step 10B. Click the description that most closely matches your product.

Step 10E: Click the radio-button next to your product code, and then click "Continue." Skip to Step 12A.

NOTE: If more than one page of potential product matches is generated, make sure to review all pages until you find the product code that matches your device.

Register Your Facility Get Help ?

## View Listing Product Codes

**FACILITY:** SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

If an exempt product code appears with the selection box grayed out and not selectable, please check to make sure you do not already have a listing for that product code. If you do have an exempt listing for the product code, you must return to the main menu and select Change, Deactivate, or Reactivate Listings, and add any new information to your existing listing.

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Displaying Page 1 of 1

	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input checked="" type="radio"/>	CLINICAL CHEMISTRY	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT	1	510(k) exempt



Step 11: If a valid premarket submission number was entered, the product code will display. If the product code is correct, click "Continue". If you think that an incorrect product code is showing for the premarket submission number entered, contact [reglist@CDRH.FDA.GOV](mailto:reglist@CDRH.FDA.GOV) for assistance.

If an incorrect premarket submission number was entered, click "Back" to enter the correct number.

Proceed to Step 12A.

Register Your Facility Get Help ?

## View Listing Product Codes

**FACILITY:** SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA

Product codes for the non-exempt device K123456

Medical Specialty	Product Code	Device/Product Name	Class
GENERAL AND PLASTIC SURGERY	FRO	Dressing, wound, drug	U

Please make a selection or selections below that most closely describe your combination product:

- CONVENIENCE KIT OR CO-PACKAGE
- PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE,PATCH,ETC.)
- DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG
- DEVICE COATED OR OTHERWISE COMBINED WITH BIOLOGIC
- DRUG/BIOLOGIC COMBINATION
- SEPARATE PRODUCTS REQUIRING CROSS LABELING
- POSSIBLE COMBINATION BASED ON CROSS LABELING OF SEPARATE PRODUCTS

You will only see this area if you checked the combination product box in step 10B. Click the description that most closely matches your product.

Step 12A: On the Select Activities for Listing(s) page, select the activities related to the device at this facility, and then click "Continue."

Proceed to step 12B.

Register Your Facility Get Help ?

## Select Activities for Listing(s)

**FACILITY: SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA**

Select all activities related to this device that are performed at your facility.

- Manufacture Medical Device
- Develop Specifications But Do Not Manufacture At This Facility
- Manufacture Medical Device for Another Party (Contract Manufacturer)
- Sterilize Medical Device for Another Party (Contract Sterilizer)
- Reprocess Single-Use Device
- Repack or Relabel Medical Device
- Remanufacture Medical Device
- Export Device to the United States But Perform No Other Operation on Device
- Manufacture Device in the United States for Export Only
- Complaint File Establishment per 21 CFR 820.198
- Foreign Private Label Distributor

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

Step 12B: On the Enter Proprietary Name(s) page, enter the proprietary name(s) in the Proprietary name text box. Click "Add Proprietary Name" to move the entered name up to the Proprietary Name section. If the proprietary name needs to be confidential, check the disclosure statement box. Once all proprietary names have been added, click "Continue". Proceed to step 12C.

The screenshot shows a web form for entering proprietary names. At the top, there is a table with columns: 'Select', 'Proprietary Name', 'Confidential', 'Device labeled for use', and 'Device Identifier'. A row contains a checkbox, 'SANCO Best', 'N', and an 'EDIT' link. Below the table is a 'REMOVE SELECTED PROPRIETARY NAME(S)' button. A callout box points to the table with the text: 'Added proprietary names will display here.'

Below the table is a 'Proprietary Name\*' text input field. A callout box points to it with the text: 'Enter proprietary names here. Then click "Add Proprietary Name." Repeat for each proprietary name.'

Next to the text input is a checkbox. A callout box points to it with the text: 'Click this box if the proprietary name needs to be kept confidential.'

Below the text input is a section titled 'Labeling Information - Pilot Program Participants Only'. It contains a dropdown menu for 'Is this device labeled for use' (set to '--Please select--') and a 'Device Identifier' text input. A callout box points to this section with the text: 'Do not enter information in this section, unless you are part of the Pilot Program.'

At the bottom of the form are two buttons: 'ADD PROPRIETARY NAME' and 'CLEAR'. Below these is a section titled 'Upload Proprietary Names Using Spreadsheet'. It contains a list of instructions: 'Click here to download a sample spreadsheet in the correct format.', 'Enter the proprietary names into the sample Excel spreadsheet or an Excel spreadsheet formatted exactly as shown in the sample.', 'Be sure to save your spreadsheet to a place you will remember on your computer.', and 'Click "Browse" to go to the saved spreadsheet, then click "Upload".'. A callout box points to this section with the text: 'If you have a large list of proprietary names, you can use the option for uploading them in a spreadsheet.'

At the very bottom of the page are three navigation buttons: '< BACK', '< CANCEL - RETURN to MAIN MENU', and '> CONTINUE'.


Step 12C: On the Add Importer(s) page, if the facility is currently exporting the device to the U.S., click "Add New Importers". Proceed to step 12D.

If the facility is not yet exporting to the U.S. or is a specifications developer that does not ship the product from this location to the U.S., click the box indicated below and then click "Continue". Proceed to step 13.

The screenshot shows a web interface for "Register Your Facility" with the sub-header "Add Importer(s)". A "Get Help" link with a question mark icon is in the top right. A box displays the facility name: "FACILITY: SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA". Below this, a blue instruction reads: "You must identify at least one importer of this product to complete your listing if the below check box is not checked. Please click 'ADD NEW IMPORTER(S)' to identify any importers of this product that are known to you." A checkbox is present, with a callout box pointing to it containing the text: "Click this box only if the device is not yet being exported to the U.S. or if the establishment is a specification developer that does not ship directly to the U.S." Below the checkbox is a button labeled "> ADD NEW IMPORTER(S)". At the bottom, there are three buttons: "< BACK", "< CANCEL - RETURN to MAIN MENU", and "> CONTINUE".

Step 12D: In an initial registration, there are no existing importers listed for you to choose from.

On the Identify Facilities From Which Importer Receives or Offers Product page, click "Add New Importer". Proceed to step 12E.

Register Your Facility Get Help 

## Identify Facilities From Which Importer Receives or Offers Product

**Important:** Foreign facilities must identify who imports their product or offers their product for import. You will first identify the importers for your product, and you will then identify which of your facilities the importer receives the product from on a different screen.

- Review the importers in the table below, if shown, and delete any that do not import this product from the facility you are currently registering
- Add Importers already identified on other listings as importing other products from your company by clicking "IMPORTERS PREVIOUSLY IDENTIFIED".
- Add new or additional importers by clicking "ADD NEW IMPORTER"

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)
NEW LISTING	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT


There are currently no importer(s) identified for this listing. Please click "ADD NEW IMPORTER" or "IMPORTERS PREVIOUSLY IDENTIFIED" on other listings to add all importers of this product from the facility you are registering. You must identify at least one importer or click BACK and check the box on the preceding page indicating that your product is not currently being imported into the United States OR that you are a specification developer who does not export your product from this establishment.

< BACK> IMPORTERS PREVIOUSLY IDENTIFIED> ADD NEW IMPORTER> CONTINUE< CANCEL - RETURN to MAIN MENU

Step 12E: On the Importer Information page, you will be asked to indicate whether or not the importer being identified is registered with the FDA. Click on the radio button for either Yes or No and then "Continue".

If you indicated No, proceed to step 12F.

If you indicated Yes, proceed to step 12G.

Register Your Facility Get Help 

## Importer Information

**Important Notice:** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, the 'Bioterrorism Act') requires each foreign establishment to provide, as part of its registration, the name of each known importer of the establishment's devices and the name of each person who imports or offers to import the device into the United States.

There are two types of importers you must identify - those that are required to register with FDA that take first possession of the device and those who further the marketing of the device such as agents and brokers that are not required to register.

Is the facility that imports your medical device that you are currently identifying registered with FDA?

YES NO

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Step 12F: On the Enter Importer Information Page, select the importer country from the drop down menu and then enter the importer's address. If known, enter the facility phone number, fax number, email address, and DUNS number. You are also required to select the importer type from the drop down menu. After you enter the importer information, click "Continue". Proceed to step 12I.

Register Your Facility  
**Enter Importer Information** Get Help ?

Please enter the information below for the importer or company that offers this product for import. You must also select the type of importer from the drop down list below. If this importer takes first title to the device in the United States, please click "BACK" and answer "Yes" to the question regarding whether the importer is registered.

**Fields marked with an asterisk (\*) are required.**

Importer Country/Area:\*

Facility Name:\*

Address Line 1:\*

Address Line 2:

Zip Code:\*

City:\*

State:\*

Phone:

Fax:

E-mail Address:

DUNS Number:  
(Enter only the 9-digit number, no dashes or other characters)

Importer Type:  
If other, please provide brief description:

Select importer country from drop down menu and then enter the importer's address.

If known, provide the facility phone /fax numbers, facility email address, and DUNS number.

Select importer type from the drop down menu.

After you have entered the Importer information, click "Continue".

Step 12G: On the Search For Importer(s) page, enter as little information as possible to narrow the search results. Enter only the registration number and do not enter information into the other fields. If you do not know the registration number, enter only the name of the facility and do not enter information into the other fields. You can also search by address. After you have entered your search criteria, click "Search Importers". Proceed to step 12H.

NOTE: For a registered importer to display in your search results, the importer must have an active registration for the current fiscal registration year.

Register Your Facility Get Help ?

## Search For Importer(s)

Enter your search criteria, then click SEARCH IMPORTERS. You should enter as little information as is possible to identify the importer as all criteria, not any criteria, that is entered must match our database. If you enter a registration number, do not enter any information in any of the other fields. As with the registration number, entering the facility name by itself is normally enough information to identify the company, therefore, unless there are several establishments with the same name, you should not enter any information in any of the other fields.

You can search by any of the fields below, but the more criteria you identify, the smaller the number of results you will get. The DRLM search mechanism uses an implied "And."

You can also search for registered medical device establishments at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

Registration Number:

Facility Name:

Address:

Importer Country/Area: Please select

Postal Code:

City:

State: [Choose a State / Province / Territory](#)

For the best results, search by registration number only.

Searching by name may result in multiple search results.

When searching by name, only enter the address if you need to narrow search results.



Step 12H: After your search results are displayed, click on the radio button for the facility that is importing your device and then click "Add Importer To Listing". Proceed to step 12I.

Register Your Facility Get Help 

## Search For Importer(s)

Please select the facility importing or offering to import this medical device, then click ADD IMPORTER TO LISTING

	Registration Number	Importer Name	Address
<input checked="" type="radio"/>	2124215	Boston Scientific Corporation	4100 Hamline Ave N, Saint Paul Minnesota, 55112 UNITED STATES

[← BACK TO SEARCH](#) [> ADD IMPORTER TO LISTING](#)

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Step 12I: You will be returned to the Identify Facilities From Which Importer Receives or Offers Product page.

If the displayed importer is correct, and you do not need to add another importer for this device, click "Continue" and proceed to step 13.

If the displayed importer is incorrect, click the radio button next to the incorrect importer and then click "Delete Importer".

To add additional importers or to replace a deleted importer, click "Add New Importer" and go back to step 12E.

Register Your Facility Get Help ?

## Identify Facilities From Which Importer Receives or Offers Product

**Important:** Foreign facilities must identify who imports their product or offers their product for import. You will first identify the importers for your product, and you will then identify which of your facilities the importer receives the product from on a different screen.

- Review the importers in the table below, if shown, and delete any that do not import this product from the facility you are currently registering
- Add Importers already identified on other listings as importing other products from your company by clicking "IMPORTERS PREVIOUSLY IDENTIFIED".
- Add new or additional importers by clicking "ADD NEW IMPORTER"

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)
NEW LISTING	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT

The importer(s) below has been previously identified as importing this device. If this importer does not import this device from the facility you are currently registering, please delete the importer by clicking the radio button and then clicking DELETE IMPORTER.

Importer Name	Address
<input type="radio"/> Boston Scientific Corporation	4100 Hamline Ave N, Saint Paul, Minnesota, 55112 UNITED STATES

Click on this button to delete an importer that has been identified as incorrect.

Only click on the radio button when identifying an importer that is being deleted.

Step 13: On the Review Listings Summary page, review the device listing and click "Continue" if you do not have any more devices to be listed. Proceed to Step 14A.

To add more devices to the list, click "Add New Product", go to step 10A.

Register Your Facility  
**Listings Summary** Get Help ?

**FACILITY:** SANCO ASIA, DONGGUAN CITY , GUANGDONG , CHINA

- Review the listings in the "Added Listing(s)" table below.
- Make updates by selecting a listing and clicking "Edit Selected Listing".
- Add more listings by clicking "Add New Product".

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Proprietary Names	Importers
<input checked="" type="radio"/> New Listing	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT	Manufacturer	<a href="#">View All</a>	Boston Scientific Corporation

> REMOVE this PRODUCT from FACILITY'S LISTINGS

< Go to OWNER OPERATOR LIST

< CANCEL - RETURN to MAIN MENU

> EDIT SELECTED LISTING

> ADD NEW PRODUCT

> CONTINUE

Step 14A: On the **top half** of the Registration Review page, review the facility and contact person information for accuracy. If the information is not accurate, click the appropriate "Edit" button and follow the prompts to make corrections. Proceed to Step 14B.

Register Your Facility Get Help ?

## Registration Review

**FACILITY:** *SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA*

Facility > EDIT

Registration Number:  
Initial Importer: N  
Facility Name: SANCO Asia  
Address: 12345 SANCO way  
Dongguan City , Guangdong , 11223 , CHINA  
DUNS Number:  
Foreign Trade Zone: N  
Facility URL:  
Other Business Trade Name(s):

### Owner/Operator Information

Contact Name: Istvan Nagy  
Company: SANCO  
Address: 12345 Rockville Pike  
Rockville , MARYLAND , 20852 , UNITED STATES  
Telephone: 301 - 7987814  
Fax:  
E-mail: [steve.nagy@fda.hhs.gov](mailto:steve.nagy@fda.hhs.gov)  
DUNS Number:

Official Correspondent Information > EDIT

Contact Name: Istvan Nagy  
Company: SANCO  
Address: 12345 Rockville Pike  
Rockville , MARYLAND , 20852 , UNITED STATES  
Telephone: 301 - 7987814  
Fax:  
E-mail: [steve.nagy@fda.hhs.gov](mailto:steve.nagy@fda.hhs.gov)  
DUNS Number:

Step 14B: On the **bottom half** of the Registration Review page, review U.S. Agent and Device Listings. If the information is not accurate, click the appropriate “Edit” button and follow the prompts to make corrections. If / when all information is correct, click the box next to the certification statement, then click “Submit.” Proceed to Step 15.

United States Agent Information > EDIT

Contact Name:	Istvan Nagy
Contact Title:	Mr
Business Name:	SANCO
Address:	12345 Rockville Pike Rockville , Maryland , 20852 , UNITED STATES
Phone:	301 - 7987814
Fax:	
DUNS Number:	
E-mail Address:	steve.nagy@fda.hhs.gov

Device Listings > ADD, EDIT OR DELETE

Listing Number	Premarket Submission Number/Type	Product Codes	Device Name	Activities	Importers
New Listing	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT	Manufacturer	Boston Scientific Corporation

**Certification Statement**

By clicking the Submit button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

**Who Must Pay:** All establishments must pay the annual registration fee prior to registering or re-registering.

If you have already registered for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

< CANCEL - RETURN to MAIN MENU

> SUBMIT

Step 15: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) and click "Submit." Proceed to Step 16.

Register Your Facility Get Help ?

## Enter Payment Confirmation Number

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is a 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2014, the PCN begins with "14".

You must have a separate PCN for each registration shown. If you have not yet paid your annual registration user fee, you must visit the [FDA User Fee website](#) and pay for each registered facility prior to completing registration. If you have paid for your registration(s) and do not have your PIN and PCN, you can display your numbers by visiting the [FDA User Fee website](#)

Sample PIN - PCN:50000000-14000000

Registration Number	Address	PIN	PCN
New registration being created	SANCO Asia, 12345 SANCO way, Dongguan City, Guangdong CHINA	<input type="text" value="50090565"/>	<input type="text" value="14206806"/>

Step 16: The Registration Confirmation page displays the registration information you have entered. Return to the main menu to continue other registration and listing actions or return to the Account Management page to log out of the system. Proceed to Step 17.

Register Your Facility

**Registration Confirmation**

**FACILITY:** SANCO ASIA, DONGGUAN CITY , GUANGDONG , CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

**The Owner/Operator Number for this Registration is: 10048405.**

**Facility**

Registration Number:

Initial Importer: N

Facility Name: SANCO Asia

Address: 12345 SANCO Way  
Dongguan City , Guangdong , 11223 , CHINA

DUNS Number:

Foreign Trade Zone: N

**Owner/Operator Information**

Contact Name: Istvan Nagy

Company: SANCO

Address: 12345 Rockville Pike  
Rockville , MARYLAND , 20852 , UNITED STATES

Telephone: 301 - 7967814

E-mail: steve.nagy@fda.hhs.gov

**Official Correspondent Information**

Contact Name: Istvan Nagy

Company: SANCO

Address: 12345 Rockville Pike  
Rockville , MARYLAND , 20852 , UNITED STATES

Telephone: 301 - 7967814

E-mail: steve.nagy@fda.hhs.gov

**United States Agent Information**

Contact Name: Istvan Nagy

Contact Title: Mr

Business Name: SANCO

Address: 12345 Rockville Pike  
Rockville, Maryland, 20852, UNITED STATES

Phone: 301-7967814

E-mail Address: steve.nagy@fda.hhs.gov

**Device Listings**

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities	Importers
D226459	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT	Manufacturer	Boston Scientific Corporation

[← RETURN to MAIN MENU](#)

[← RETURN to ACCOUNT MANAGEMENT](#)

Step 17: A confirmation email will be generated and sent to you with the following information:

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
**Center for Devices and Radiological Health**  
**10903 New Hampshire Ave., WO66 Room 2621**  
**Silver Spring, Maryland 20993-0002**

March 13, 2015

Name of Official Correspondent   ISTVAN NAGY  
Address of Official Correspondent  12345 ROCKVILLE PIKE  
ROCKVILLE, MARYLAND 20852  
UNITED STATES  
[STEVE.NAGY@FDA.HHS.GOV](mailto:STEVE.NAGY@FDA.HHS.GOV)

Owner Operator Number           10048405

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name               SANCO ASIA  
Establishment Address           12345 SANCO WAY  
DONGGUAN CITY, GUANGDONG 11223  
CHINA

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. You will be notified of your official registration number within 90 days.

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.

For inquiries about the status of your registration or assignment of your registration number, please contact the Registration and Listing Program Office at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) or calling (301) 796-7400.

If you have any questions regarding FDA policy related to the Registration and Listing program, please contact the Registration and Listing staff at [device.reg@fda.hhs.gov](mailto:device.reg@fda.hhs.gov) or calling (301) 796-7400.