FURLS Device Registration & Listing

Annual Registration

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

Division of Industry and Consumer Education (DICE)

Instructions for

Annual Registration
This tutorial should only be used when 1) reregistering a facility that has an existing registration, that is currently active and 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN).

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

Enter the existing account ID and password that are associated with the registration record, click “I Understand” and then click on the Login button.

Note: If you are unable to find the correct account information, contact reglist@CDRH.FDA.GOV for assistance. You cannot access an existing registration if you create a new account.

Proceed to Step 2.
Step 2: Click "Device Registration & Listing Module" (DRLM) to access your registrations. Proceed to Step 3.
Step 3: Review “Important Messages” on the DRLM Home page.
Proceed to Step 4.

**Note:** You must pay the fee to receive your Payment Identification Number (PIN) & Payment Confirmation Number (PCN) before you can complete the annual registration.

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**Important Notice:** You must visit the [FDA User Fee website](http://www.fda.gov/Training/CDRHLearn/default.htm) 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.

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**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/default.htm](http://www.fda.gov/Training/CDRHLearn/default.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 2017 is $3,382.** 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/MDUFAIII/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm).

You must pay the fee before registering a new establishment or updating your existing registration(s) and/or listing(s) for FY 2017. 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.

Click on this link if you need to pay the fee to get your PIN & PCN. Clicking the link will log you out of FURLS. After you get your PIN & PCN, you will need to log back into FURLS to complete the annual registration.
Step 4: Click on "Annual Registration" link in the DRLM menu. Proceed to Step 5.
Step 5: You will see a list of all of your facilities that need to complete the annual registration. For each facility, that has activities that require registration, click on the blue action icon.

Proceed to Step 8.

If a facility no longer has activities that require registration, click on the red action icon to deactivate the registration. Proceed to step 6.
Step 6: Review the facility information to confirm that you have selected the correct registration for deactivation. If correct, click the certification statement box and then click “Deactivate Selected Registration”.

Proceed to step 7.

If you have not selected the correct registration for deactivation, click on “previous” to return to the facility selection page and return to Step 5.

Return to Step 5.
Step 7: You will now see a registration deactivation confirmation screen.

Note: If you want to have a copy of the deactivation confirmation for your records, print a copy now. You will not be able to return to this confirmation page later.

If you have other annual registrations to complete, click on “Back to Registration List”.

Return to Step 5.

If you do not have any other annual registrations to complete, you may select other actions from the DRLM menu or you may return to the Account Management page to log out of FURLS.

Registration Deactivation Confirmation

The Owner/Operator Number for this Registration is: 10054564.

Print a copy of this transaction for your records.

<table>
<thead>
<tr>
<th>Status</th>
<th>Name and Address</th>
<th>Registration/FEI Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactive</td>
<td>SANCO Barbados 12345 Bajan Way</td>
<td>Registration Number Not Yet Assigned</td>
</tr>
<tr>
<td></td>
<td>St. James, Saint James, 00000, BARBADOS</td>
<td></td>
</tr>
</tbody>
</table>

To return to your list of facilities that need to complete the annual registration.
Step 8: Review each section of the Registration Review page for accuracy.

Below is an example of a domestic facility Registration Review page. Each section will be discussed on the following pages.
Note: if you are not registered as Initial Importer, you will not see the Imported Products and Manufacturers section of the screen
Below is an example of a foreign facility Registration Review page. Each section will be discussed on the following pages.
Facility Information
Registration Number: N
Initial Importer: N
Facility Name: SANCO Barbados
Address: 1234 Bigan Way
          St. James, Saint James, 00000, BARBADOS
DUNS Number: N
Foreign Trade Zone: N
Facility URL: Other Business Trade Name(s)

Owner/Operator Information
Owner/Operator Number: 10054564
Contact Name: Istvan Nagy
Company: SANCO
Address: 1234 Rockville Pike
          Rockville, MARYLAND, 20852, UNITED STATES
          301-7701234
Phone: E-mail: steve.nagy@fda.hhs.gov
Fax: DUNS Number:

Official Correspondent Information
Contact Name: Istvan Nagy
Company: SANCO
Address: 1234 Rockville Pike
          Rockville, MARYLAND, 20852, UNITED STATES
          301-7701234
Phone: E-mail: steve.nagy@fda.hhs.gov
Fax: DUNS Number:

United States Agent Information
Contact Name: Istvan Nagy
Contact Title: Mx
Business Name: SANCO
Address: 1234 Rockville Pike
          Rockville, Maryland, 20852, UNITED STATES
          301-7704321
Phone: Fax: DUNS Number: E-mail Address: steve.nagy@fda.hhs.gov

Device Listings

<table>
<thead>
<tr>
<th>Listing Number</th>
<th>Premarket Submission Number/Type</th>
<th>Product Code(s)</th>
<th>Device Name(s)</th>
<th>Activities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D271630</td>
<td>Exempt</td>
<td>ECK</td>
<td>Cylinder, compressed gas, and valve</td>
<td>Repackager/Relabeler</td>
<td>SANCO</td>
</tr>
<tr>
<td>D271823</td>
<td>Exempt</td>
<td>SXE</td>
<td>ALGESIMETER, MANUAL</td>
<td>Repackager/Relabeler</td>
<td>SANCO</td>
</tr>
</tbody>
</table>

Certification Statement

[ ] By clicking the Reactivate Registration 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 501(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.
Section 1: Facility Information (for domestic and foreign)

If you need to edit facility information, click on the edit icon to go to the edit page.

After making edits, click on “next” to return to the Registration Review page to complete the review of the registration and listing information.
Section 2: Owner/Operator Information & Official Correspondent Information

If you need to update either the owner/operator or official correspondent information, you must click on the FURLS Home link, located at the top right corner of your screen. Clicking on the FURLS Home link will take you out of the annual registration process.

Instructions for updating the owner/operator and official correspondent information is available here:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm#11

After making updates, return to Step 2 to complete the Annual Registration process.

If you do not need to update either the owner/operator or official correspondent information, proceed to the next section below, U.S. Agent information (foreign establishments only). Otherwise, proceed to section 4 to edit Device Listings.
Section 3: U.S. Agent Information (Foreign Registrations Only)

If you need to edit the U.S. Agent information, click on the edit icon to go to the edit page.

![Edit page](image)

Clicking the edit icon will take you to the edit page below.

Edit page:

![U.S. Agent Information](image)

After making edits, click on “Review Changes” to return to the Registration Review page to complete the review of the registration and listing information.
**IMPORTANT NOTE:** A new feature is being added to FURLS/DRLM beginning with the Fiscal Year (FY) 2018 registration cycle. Each U.S. Agent will receive an email that notifies her/him of the need to verify that she/he agrees to act in this capacity for your registered establishment once the facility registration is complete. The email will provide instructions on how to access and verify the information in FURLS/DRLM. If she/he fails to verify, then FDA will inform the establishment’s Official Correspondent and Owner/Operator contact person that a new U.S. Agent must be identified. **Failure to provide valid U.S. Agent information will result in the deactivation of your registration.** Carefully review this section for accuracy and make any needed corrections before you submit your annual registration. You should consider notifying your U.S. agent of this new verification process, so she/he responds to the FDA email.
Section 4: Device Listings

If you need to edit listing information, click on the edit icon to go to the edit page.

You will have the choice of editing the existing listing or removing the existing listing. You also may add a new listing from either the existing owner/operator list or by creating a new listing.

Edit page:

After making edits, click on “Next” to return to the Registration Review page to complete the review of the registration and listing information.

If you have finished reviewing your registration and listing information, please proceed to Section 6: Certification Statement

Important Note about creating a new listing: A new feature is being added beginning with FY 2018 registration cycle that will allow you to create two listings for a product – one
listing for products made in the United States and another listing for the products manufactured for export only. You will no longer be able to add the “U.S. Manufacturer for Export Only” establishment type to an existing listing for a product. You will now be required to create a separate listing for the export only model of the device.

Section 5: Imported Products and Manufacturers (Initial Importers Only)

If you need to edit the imported products information, click on the edit icon to go to the edit page.

If the facility is no longer importing an identified product, you will be able to remove that product. You also may add a new imported product from either the existing owner/operator list or by identifying a new product.

Edit page:

Imported Products Summary

When you have finished making your edits to the Imported Products Summary page, click on “Next” to return to the Registration Review page to complete the
review of the registration and listing information.

Section 6: Certification Statement (for domestic and foreign)

If all information is accurate, check the certification statement box, found at the bottom of the Registration Review page, and then click “Submit”.

Proceed to Step 9.
Step 9: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) previously received and click “Submit.” Proceed to Step 10.

Enter Payment Confirmation Number

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

The PIN is an 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2017, the PCN begins with “17”

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: 50000000-17000000

<table>
<thead>
<tr>
<th>Registration Number</th>
<th>Address</th>
<th>PIN</th>
<th>PCN</th>
</tr>
</thead>
</table>
| Active, Waiting for Registration Number Assignment | SANCO  
1234 Rockville Pike  
Rockville, Maryland, 20852, UNITED STATES | 50000000 | 17000000 |
Step 10: The Annual Registration Successful page displays the registration information you have entered.

Annual Registration Successful

Facility: SANCO, Rockville, Maryland, UNITED STATES

You have successfully updated your registration and listing information for 2017. Your registration will be valid through December 31, 2017. Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2017.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at regist@cdhlfsa.gov.

The Owner/Operator Number for this Registration is: 10054564.

Facility Information

<table>
<thead>
<tr>
<th>Registration Number:</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Importer:</td>
<td>SANCO</td>
</tr>
<tr>
<td>Facility Name:</td>
<td>1234 Rockville Pike</td>
</tr>
<tr>
<td>Address:</td>
<td>Rockville, Maryland, 20852, UNITED STATES</td>
</tr>
<tr>
<td>DUNS Number:</td>
<td>N</td>
</tr>
<tr>
<td>Foreign Trade Zone:</td>
<td></td>
</tr>
<tr>
<td>Facility URL:</td>
<td></td>
</tr>
<tr>
<td>Other Business Trade Name(s):</td>
<td></td>
</tr>
</tbody>
</table>

Owner/Operator Information

<table>
<thead>
<tr>
<th>Owner/Operator Number:</th>
<th>10054564</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name:</td>
<td>Istvan Nagy</td>
</tr>
<tr>
<td>Company:</td>
<td>SANCO</td>
</tr>
<tr>
<td>Address:</td>
<td>1234 Rockville Pike</td>
</tr>
<tr>
<td>Telephone:</td>
<td>301 - 770-1234</td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td><a href="mailto:steve.nagy@fda.hhs.gov">steve.nagy@fda.hhs.gov</a></td>
</tr>
<tr>
<td>DUNS Number:</td>
<td></td>
</tr>
</tbody>
</table>

Official Correspondent Information

| Contact Name:          | Istvan Nagy |
| Company:               | SANCO |
| Address:               | 1234 Rockville Pike |
| Telephone:             | 301 - 770-1234 |
| Fax:                   |   |
| E-mail:                | steve.nagy@fda.hhs.gov |
| DUNS Number:           |   |

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<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>D123456</td>
<td>Preamendment</td>
<td>BCX</td>
<td>Cylinder, compressed gas, and valve</td>
<td>Repackager/Relabel</td>
</tr>
</tbody>
</table>

Imported Products and Manufacturers

<table>
<thead>
<tr>
<th>Manufacturer(s) Name</th>
<th>Address</th>
<th>Product Code</th>
<th>Device Name</th>
<th>Premarket Submission Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>COLAB DESIGN PTY LTD</td>
<td>Unit 5, 15-17 Gibbs Street, Chatswood, Sydney, New South Wales, 2057, AUSTRALIA</td>
<td>HQY</td>
<td>Sunglasses (non-prescription including photosensitive)</td>
<td></td>
</tr>
</tbody>
</table>
Congratulations! This screen means the annual registration has been completed.

A Confirmation email will be sent to the official correspondent with similar information as indicated below:

Dear Istvan Nagy:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2017:

Registration Number:
Owner Operator Number: 10054564
SANCO
1234 Rockville Pike
ROCKVILLE, MD 20852
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2017. Registration for 2018 will be conducted between October 1 and December 31, 2017.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

You may select another action from the DRLM menu or you may return to the Account Management page to log out of FURLS.