

# **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](mailto:reglist@CDRH.FDA.GOV) for assistance. You cannot access an existing registration if you create a new account.

Proceed to Step 2.

The screenshot shows the 'ONLINE ACCOUNT ADMINISTRATION (OAA)' page for 'FDA Industry Systems'. The page has a dark blue header with the FDA logo and the text 'ONLINE ACCOUNT ADMINISTRATION (OAA)'. Below the header, there is a 'System Status' button. The main content area is divided into two sections: 'Login' and 'New User'. The 'Login' section has a form with 'Account ID' and 'Password' fields, an 'I understand.' checkbox, and a 'Login' button. The 'New User' section has a 'Create New Account' button. A callout box points to the 'Login' section with the text: 'Enter the existing account ID and password that are associated with the registration, click "I Understand" and then click on the Login button.' Another callout box points to the 'Create New Account' button with the text: 'Annual registration is not an option when creating a new account. If your facility has not previously been registered, you should not continue with this tutorial.' The page also contains a 'WARNING' section and a 'CTP Registration and Listing' section. The footer of the page includes the FDA logo and links for 'Accessibility', 'Browser Requirements', 'FAQ', 'Help Desk', and 'Privacy'.

Step 2: Click "Device Registration & Listing Module" (DRLM) to access your registrations. Proceed to Step 3.

## 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 **san45041** 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.

### Registration and Listing Programs

#### Food

Acidified/Low-Acid Canned Foods Registration and Process Filing

Shell Egg Producer Registration

Dairy Listing Module

Structure/Function Claims Notification

New Dietary Ingredient Notification

#### Medical Devices

Device Registration and Listing Module

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.

**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.

#### 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> 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>.

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](mailto:userfees@fda.gov).

FDA primarily communicates with firms by email. To ensure you receive the correct email for your account, please click on the FURLS Home link at the top of this page. Then click on

Please note a new feature has been added to the "Download Your Listing Information", w

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.

The screenshot shows the DRLM Home page with a navigation menu on the left. The 'Annual Registration' link is highlighted with a red box. A callout bubble points to this link with the text 'Click on "Annual Registration"'. To the right, there is a yellow 'Important Notice' box and an 'Important Messages' section.

DRLM Home

**Annual Registration** ▾

- Annual Registration

**Facility Registration** ▾

- Register a New Medical Device Facility
- Change Registration Information for a Facility
- Cancel, Deactivate, or Reactivate a Facility Registration
- View Your Registration and Listing Information
- Change the Official Correspondent for a Facility

**Facility Ownership** ▾

- Transfer Ownership of a Facility (Report Purchase)

**Medical Device Listings** ▾

- Create Listings for Medical Devices
- Download Your Listing Information
- Change, Deactivate, or Reactivate Listings
- Add/Replace Proprietary Names or Importers to Listings

**U.S. Agents Only** ▾

- Confirm U.S. Agent Notification
- View/Update U.S. Agent Information

**Important Notice:** You must visit the [FDA Us](#) not be able to register your facility and will nee

**Who Must Pay:** All establishments must pay t

**Important Messages**

Click on "Annual Registration".

The FDA Safety and Innovation Act (FDASIA) medical device provisions. MDUFA III manda

**The fee for FY 2017 is \$3,382.** There is no re <http://www.fda.gov/MedicalDevices/DeviceRe>

You must pay the fee before registering a new For assistance with paying the fee, please se

FDA primarily communicates with firms by en Edit Account Profile button on the left hand si


Please note a new feature has been added: \ third choice on the DRLM Main Menu.

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.

Facility List

To review and make any changes to the registration information of a facility, select the  icon from the "Action" column.

Show  per page [Clear Sort and Filter](#)

Name and Address	Status		Action
SANCO Barbados 12345 Bajan Way, St. James, Saint James, 00000, BARBADOS	Active, Waiting for Registration Number Assignment	Not yet assigned	 
SANCO Belize 12345 Caye Drive, Belize City, Belize, 12345, BELIZE	Active, Waiting for Registration Number Assignment		 
SANCO Zimbabwe 12345 Salisbury Lane, Harare, Harare, 00000, ZIMBABWE	Active, Waiting for Registration Number Assignment	Not yet assigned	 
SANCO 1234 Rockville Pike, Rockville, Maryland, 20852, UNITED STATES	Active, Waiting for Registration Number Assignment	Not yet assigned	 

Showing 1 to 4 of 4 entries

**For facilities that are required to reregister, click the blue action icon.**

**For facilities no longer required to register, click the red action icon.**

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.

### Registration Deactivation Review

Registration will be Deactivated

Verify the registration status of the facility you selected and click Deactivate Selected Registration.

Status	Name and Address	Registration/FEI Number
To be Deactivated	SANCO Barbados 12345 Bajan Way St. James, Saint James, 00000, BARBADOS	Registration Number Not Yet Assigned

#### Certification Statement

By clicking the Deactivate Selected 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 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

[← Previous](#)

To cancel deactivation and return to facility list, click here.

To proceed with deactivation, click here.

[Deactivate Selected Registration >](#)

**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.

Status	Name and Address	Registration/FEI Number
Inactive	SANCO Barbados 12345 Bajan Way St. James , Saint James, 00000, BARBADOS	Registration Number Not Yet Assigned

[← Back to Registration List](#)

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

# Registration Review

Facility: SANCO, Rockville, Maryland, UNITED STATES

- Review the information that you provided for your facility.
- Make changes to your facility, listing or imported products information by clicking the Edit button at the top of the corresponding section.
- Make changes to Owner/Operator or Official Correspondent information by clicking on FURLS HOME at the top right corner of your screen.

## Facility Information

[Edit](#)

Registration Number:  
Initial Importer: Y  
Facility Name: SANCO  
Address: 1234 Rockville Pike,  
Rockville, Maryland, 20852, UNITED STATES  
DUNS Number:  
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  
Telephone: 301 - 7701234  
Fax: -  
E-mail: steve.nagy@fda.hhs.gov  
DUNS Number:

## Official Correspondent Information

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

## Device Listings

[Edit](#)

Listing Number	Premarket Submission Number/Type	Product Code (s)	Device Name(s)	Activities
D271630	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler

## Imported Products and Manufacturers

[Edit](#)

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)	

## Certification Statement

- I have reviewed the registration information for the establishment and listing information for the medical devices shown on this page, made any corrections, additions or deletions as may be necessary, and certify that this information is true and correct. 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.

[← Previous](#)

[Submit →](#)

Below is an example of a foreign facility Registration Review page. Each section will be discussed on the following pages.

**Facility Information**

Registration Number:  
 Initial Importer: N  
 Facility Name: SANCO Barbados  
 Address: 12345 Bajan Way  
 St. James , Saint James , 00000 , BARBADOS  
 DUNS Number:  
 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  
 Telephone: 301 - 7701234  
 Fax:  
 E-mail: steve.nagy@fda.hhs.gov  
 DUNS Number:

**Official Correspondent Information**

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

**United States Agent Information**

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

**Device Listings**[Edit](#)

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D271630	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler SANCO
D271623	Exempt	BXL	ALGESIMETER, MANUAL	Repackager/Relabeler SANCO

**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 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

[← Back to View Registrations](#)[Reactivate Registration →](#)

## 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.

Facility Information	
Registration Number:	Y
Initial Importer:	SANCO
Facility Name:	1234 Rockville Pike
Address:	Rockville, Maryland, 20852, UNITED STATES
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

 Edit

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

### Edit page:

#### Facility Information

Location Information

Check this box if this establishment is located in a foreign trade zone

Country / Area: UNITED STATES

Address Line 1: 1234 Rockville Pike

Address Line 2 (Optional):

Facility Name: SANCO

Address Line 2 (Optional):

Phone (Optional): 1 301 7701234

Zip/Postal Code: 20852

City: Rockville

State/Province/Territory: Maryland

DUNS Number (Optional):

Facility URL (Optional):

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

Other Business Trade Name(s):

Are you an Initial Importer?  Yes  No

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.**

U.S. Department of Health and Human Services

Welcome, Istvan Nagy **FURLS HOME**

**FDA FURLS** | **DRLM**  
Device Registration & Listing Module

To update either the owner/operator or official correspondent information, click on FURLS HOME.

### Owner/Operator Information

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

### Official Correspondent Information

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

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.

United States Agent Information	
Contact Name:	William Nagy
Contact Title:	Mr
Business Name:	SANCO
Address:	12345 Rockville Pike Rockville, Maryland, 20852, UNITED STATES 301 - 7701234
Phone:	
Fax:	
DUNS Number:	
E-mail:	William@Sanco.com

 Edit

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

### Edit page:

#### U.S. Agent Information

Facility: SANCO Belize , Belize City , Belize, BELIZE

United States Agent Information

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<b>Contact Title</b>	<input type="text" value="Mr"/>	<b>Address Line 1</b>	<input type="text" value="12345 Rockville Pike"/>
<b>Contact Name</b>	<input type="text" value="William Nagy"/>	<b>Address Line 2 (Optional)</b>	<input type="text"/>
<b>Business Name (Optional)</b>	<input type="text" value="SANCO"/>	<b>Zip Code</b>	<input type="text" value="20852"/>
<b>Phone</b>	<input type="text" value="301"/> <input type="text" value="7701234"/> <input type="text"/>	<b>City</b>	<input type="text" value="Rockville"/>
	Area Phone Number Extension	<b>State</b>	<input type="text" value="Maryland"/>
<b>Fax (Optional)</b>	<input type="text"/> <input type="text"/>		
	Area Fax Number		
<b>DUNS Number (Optional)</b>	<input type="text"/>	<b>E-mail</b>	<input type="text" value="William@Sanco.com"/>
	(Enter only the 9-digit number, no dashes or other characters)		

[< Previous](#) [Review Changes >](#)

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.

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D271630	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler

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





[Edit](#)

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:




### Listings Summary

Facility: SANCO, Rockville, Maryland, UNITED STATES

- Review the listings in the "Added Listing(s)" table below.
- Make updates by selecting the appropriate icon. Select  to edit listing,  to remove listing,  to view listing proprietary names.
- Select  to add supporting document(s) to listing in preamendment status.
- Add more listings by clicking "Add New Product".

Click to create a new listing, not already in owner/operator's list of devices.

[+ Add New Product](#)

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Actions
D123456	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler	  

Click to add listing that is part of owner/operator's list of devices.

Click the pencil icon to edit existing listing. Click the x icon to remove listing.

[Go to Owner Operator List](#) [Next](#)

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.

Imported Products and Manufacturers				
Manufacturer(s) Name	Address	Pro		Premarket Submission Number
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)	

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

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

Facility: SANCO, Rockville, Maryland, UNITED STATES

- Review the products in the "Products Imported" table below.
- Add more products by clicking "Search & Add Products" or "Go to List Of MFRS Already Identified By OO".

Products Imported:

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number	Action
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)		X

Click to add product already identified by owner/operator.

Click to add product not already identified by owner/operator.

Click the x icon to remove an existing product.

< Go to List of MFRS Already Identified By OO

Search & Add Products >

Next >

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".

The screenshot shows a form titled "Certification Statement". It contains a checkbox with a checkmark, which is highlighted by a red square. A callout box points to this checkbox with the text: "The certification statement box must be checked before submitting." Below the checkbox is the following text: "I have reviewed the registration information for the establishment and listing information for the medical devices shown on this page, made any corrections, additions or deletions as may be necessary, and certify that this information is true and correct. 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." At the bottom of the form, there are two buttons: "Previous" on the left and "Submit" on the right.

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

Registration Number	Address	PIN	PCN
Active, Waiting for Registration Number Assignment	SANCO 1234 Rockville Pike Rockville, Maryland, 20852, UNITED STATES	50000000	17000000

[← Previous](#)

[Submit →](#)

## 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 [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

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

#### Facility Information

Registration Number:  
Initial Importer: Y  
Facility Name: SANCO  
Address: 1234 Rockville Pike  
Rockville, Maryland, 20852, UNITED STATES  
DUNS Number:  
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  
Telephone: 301 - 7701234  
Fax: -  
E-mail: [steve.nagy@fda.hhs.gov](mailto:steve.nagy@fda.hhs.gov)  
DUNS Number:

#### Official Correspondent Information

Contact Name: Istvan Nagy  
Company: SANCO  
Address: 1234 Rockville Pike  
Rockville, MARYLAND, 20852, UNITED STATES  
Telephone: 301 - 7701234  
Fax: -  
E-mail: [steve.nagy@fda.hhs.gov](mailto:steve.nagy@fda.hhs.gov)  
DUNS Number:

#### Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D123456	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler

#### Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)	

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](mailto: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](mailto: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.