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Medical Devices

CDRH Export Certification Application and Tracking System (CECATS) Frequently Asked Questions

1. What is CECATS?

CECATS is CDRH's web-based application for accepting requests, reviewing, processing, managing, and administering export certificates, simple notifications, and export permit letters. In the first phase, which begins in November 2012, firms will be able to submit requests for a Certificate to Foreign Government electronically through CECATS.

In 2013, CDRH expects to implement the second phase for the following requests:

- Certificates of Exportability
- Non-Clinical Research Use Only Certificates
- Simple Notifications of Medical Device Exports
- Export Permit Letter

Updates on expanded CECATS capabilities will be posted on the CDRH Device Advice[1] website.

2. Is it mandatory to use CECATS? Can paper requests be mailed to the FDA?

It is not mandatory to submit applications through CECATS. The FDA will continue to accept paper applications. CECATS allows for immediate submission and immediate notification via e-mail as well as status updates via the Internet.

Firms should choose to request a certificate through CECATS or through a mailed paper request, but not both. If a firm submits a CECATS and a mail submission for the same certificate, the FDA will process and charge for both.

3. How do I access CECATS and who do I contact if I have a problem accessing the system?

You can access CECATS after logging into the FDA Unified Registration and Listing Systems (FURLS)[2]. You must have a FURLS account ID and password to access this system. If you do not have one, please see the instructions on the FURLS website.

Should you need assistance while in FURLS please use the "Help Desk" link. If you require further assistance with your FURLS account please contact reglist@cdrh.fda.gov or call 301-796-7400.

If you need assistance on an export specific matter please send an email to cdrhcecats@fda.hhs.gov or call 301-796-7400 and press option #3.

4. Why should I use CECATS?

CECATS offers several benefits, including a reduction in certificate processing time, real-time validation and status updates.

5. Do I have to pay more for a Certificate if I use CECATS?

No, there is no additional fee for using CECATS, The original Certificate is $175 and additional copies are $15 per copy. Up to 50 pages (including the certificate, manufacturer page and attachment pages) may be submitted for the same product. Each time an increment of 50 pages is exceeded an additional fee of $175 will be charged.

6. If we use CECATS, is our company information going to remain confidential?

Yes, company information is kept confidential for both CECATS and mailed certificate requests.

7. Can I still utilize our current format for the product listings?

Yes. CECATS will also provide an option to upload the product list from a Microsoft Excel spreadsheet. This will allow you to list the product name as you would like to see it on the certificate.

8. Do I need a special account to use CECATS?

No, all registered firms should use their existing FURLS account to access CECATS. To create a FURLS account please follow the instructions on the FURLS homepage[3].

9. Can multiple individuals at one firm access CECATS to apply for certificates?

Yes, firms can create subaccounts for multiple individuals to use CECATS.

10. If I submit a request through CECATS will I receive the certificate instantly?

No. The FDA will review and validate the information provided and issue the certificate within 20 business days. We anticipate that processing time will be reduced significantly for requests submitted through CECATS.

11. Will I be able to electronically submit a return slip for mailing processed certificates?

Yes, you will be able to upload a mailing RETURN SLIP for UPS or FedEX.

12. Do I still have to provide the marketing status of my products?

You will be asked to provide the registration number for facilities on your request. The system will display all the products listed for that registration

number, and you will be able to select the products that you would like to include on your certificate.

Only products included in the listing from the FURLS account may be included on your certificate.

13. Where can I receive training?

CDRH will hold online training sessions on CECATS. These sessions are scheduled to be held via Adobe Connect[4] from 2 to 3:30 p.m. (EST) on the following dates:

- Monday, Dec. 3, 2012
- Tuesday Jan. 8, 2013
- Tuesday Feb. 5, 2013

We encourage participants to test their connection[5] prior to the webinar. Participants will not be able to enter the meeting until the host has logged in on the day of the event.

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Links on this page:

1. /MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050521.htm

2. https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1

3. https://www.access.fda.gov /oaa/logonFlow.htm;jsessionid=bW0mQmCYsGGHTpmM0HVFsNGjDyQyQKcsQvnDnff837m2xwQpyQkd!-1453744053?execution=e1s1

4. https://collaboration.fda.gov/cecats/

5. https://collaboration.fda.gov/common/help/en/support/meeting_test.htm