



# Electronic Issuance of Export Certificates from the FDA Center for Devices and Radiological Health

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October 10<sup>th</sup>, 2023

# Outline

- Electronic Certificates
- Communication efforts
- Authentication
- Demonstration
  - Center for Drug Evaluation and Research

# Electronic Export Certificate Issuance



- Export Certificates for medical devices:
  - Not required by FDA
    - If legally marketed in the U.S.
  - Often required by foreign countries to allow importation.
  - Currently printed on security paper

# Electronic Issuance of Export Certificate



- **Old process**
  - Starting January 2, 2024, Exports Certificates and documents will no longer be:
    - Printed on security paper
    - Mailed
- **Unchanged process**
  - Still requested in CDRH Export Certificate Application and Tracking System (CECATS)
- **New Process**
  - If granted after review by FDA:
    - Requester receives an email with instructions
    - One time access to print or save a PDF within 45 days



# Electronic Export Certificate Issuance Communication

- July 10, 2023
  - 6 months prior to official launch
  - Officially announced transition to electronic certificates
  - Posted on FDA.Gov
    - Under Letters to Industry ([Electronic Export Documents – Letter to Industry | FDA](#))



# Exporting Medical Devices



## Exporting Medical Devices

Devices Not Exported From the United States

Types of Export Certificates

Other Export Documents

How to Request Export Certificates or Permits and How to Submit Simple Notifications

Exporting Medical Devices Frequently Asked Questions (FAQs)

Update: July 10, 2023

In December 2023, the FDA will begin transitioning from paper export documents for medical devices to electronic export documents. For requests received on or before December 15, 2023, we will continue to issue paper certificates. For requests received on or after December 16, 2023, the FDA intends to issue paper certificates only if our review is completed prior to January 2, 2024. All certificate request reviews completed by the FDA after January 2 will be issued electronically. Export documents for human medical device products that CDRH regulates will be issued to requestors electronically as downloadable PDFs through the CDRH Export Certification Application and Tracking System (CECATS). Certificates may be validated by foreign governments and others using the FURLS Export Certificate Validator (FECV) database for the time period they are in effect. The FECV will be accessed using the URL address or QR code displayed at the bottom of each certificate. The change from paper to PDF export documents will improve efficiency in issuing export documents, reduce the amount of time it takes for a manufacturer to receive export certificates or Export Permit Letters, and decrease environmental burden. Read [Electronic Export Documents – Letter to Industry](#).

Content current as of:  
07/10/2023

**Regulated Product(s)**  
Medical Devices  
Radiation-Emitting Products



# CECATS CDRH Export Certification Application and Tracking System

## CDRH Export Certification Application and Tracking System Main Menu



CECATS Home

CECATS Home

Enter New Application

Modify Application

Search Application

### FORM APPROVAL: OMB NO.0910-0498

Expiration date: 4/30/2024  
See OMB Statement at end of form.

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**Please Note:** The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

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# Electronic Export Certificate Issuance Communication

- On going efforts:
  - Meetings
  - Talks
  - Email inquiries
    - [EXPORTCERT@CDRH.FDA.GOV](mailto:EXPORTCERT@CDRH.FDA.GOV)





# Electronic Certificate Predicates

- FDA Center currently issuing e-certs:
  - Center for Veterinary Medicine (CVM)
    - Launched in 2020
  - Center for Food Safety and Applied Nutrition (CFSAN)
    - Launched in 2020
  - Center for Drug Evaluation and Research (CDER)
    - Launched in 2021

## Countries to which other centers have issued electronic certificates

Albania	Costa Rica	Kazakhstan	Paraguay	Uruguay
Algeria	Curaçao	Kenya	Peru	Uzbekistan
Argentina	Denmark	Korea (South)	Philippines	Venezuela (Bolivarian Republic)
Armenia	Dominican Republic	Kosovo	Poland	Viet Nam
Aruba	Ecuador	Kuwait	Portugal	Yemen
Australia	Egypt	Kyrgyzstan	Qatar	
Austria	El Salvador	Lebanon	Romania	
Azerbaijan	Ethiopia	Libya	Russian Federation	
Bahamas	Finland	Luxembourg	Rwanda	
Bahrain	France	Macao, SAR China	Saudi Arabia	
Bangladesh	Gabon	Macedonia, Republic of	Serbia	
Belarus	Georgia	Malaysia	Singapore	
Belgium	Germany	Maldives	Sint Maarten	
Belize	Ghana	Mali	South Africa	
Bermuda	Greece	Mauritius	Spain	
Bolivia	Guatemala	Mexico	Sri Lanka	
Bosnia and Herzegovina	Guyana	Moldova	Suriname	
Botswana	Haiti	Mongolia	Sweden	
Brazil	Honduras	Montenegro	Switzerland	
Brunei Darussalam	Hong Kong, SAR China	Morocco	Taiwan, Republic of China	
Bulgaria	India	Myanmar	Tanzania, United Republic of	
Cambodia	Indonesia	Namibia	Thailand	
Cameroon	Iran, Islamic Republic of	Nepal	Trinidad and Tobago	
Canada	Iraq	Netherlands	Tunisia	
Caribbean	Ireland	New Zealand	Turkey	
Cayman Islands	Israel	Nicaragua	Turkmenistan	
Central African Republic	Italy	Nigeria	Uganda	
Chile	Jamaica	Oman	Ukraine	
China	Japan	Pakistan	United Arab Emirates	
Colombia	Jordan	Panama	United Kingdom	

# Electronic Certificate Validation

- FURLS Export Certificate Validator (FECV):
  - Allows direct validation from FDA databases
  - Accessible:
    - Within seconds
    - Via URL web address; or
    - Quick Response (QR) code
    - No account or software download needed
  - Displays the entire content of the certificate
    - secure

# Electronic Certificate Validation

- FURLS Export Certificate Validator (FECV) demonstration
  - Center for Drug Evaluation and Research (CDER) data



# Summary

- CDRH is transitioning to Electronic certificates
  - January 2<sup>nd</sup>, 2024
  - Already in use by
    - CDER, CFSAN, CVM
- Authentication
  - Primary mode-FECV
  - Apostille-available if needed





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