Exporting Medical Devices

FDA Small Business
Regulatory Education for Industry (REdI)
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Learning Objectives

- Explain what is an export certificate
- List types of export certificates or documents available
- Identify export requirements
- Outline the application process

Poll

Do you export devices?

1. Yes
2. No
3. Not sure

Background

- FDA does not restrict sales of devices that can be legally marketed in the United States
- During international trade, devices may need to demonstrate compliance to applicable regulations

Purpose of Export Documents

Attest:

- Marketing status of the device in United States
- Compliance to **current Good manufacturing Practices** (cGMP)-21 Code for Federal Regulation part 820 (21 CFR 820)

Export Law

- **Food Drug & Cosmetic (FD&C) Act**
  - Chapter VIII
    - Section 801
    - Section 802

Export Reform and Enhancement Act (EREA) of 1996

Modified section 801 and replaced section 802 to allow:

- Manufacturers to request certificate for medical devices they export
- FDA to issue certificate, or refuse request if certain requirements are not met
- FDA to charge a fee for issuing export certificates within 20 days

Roles and Responsibilities

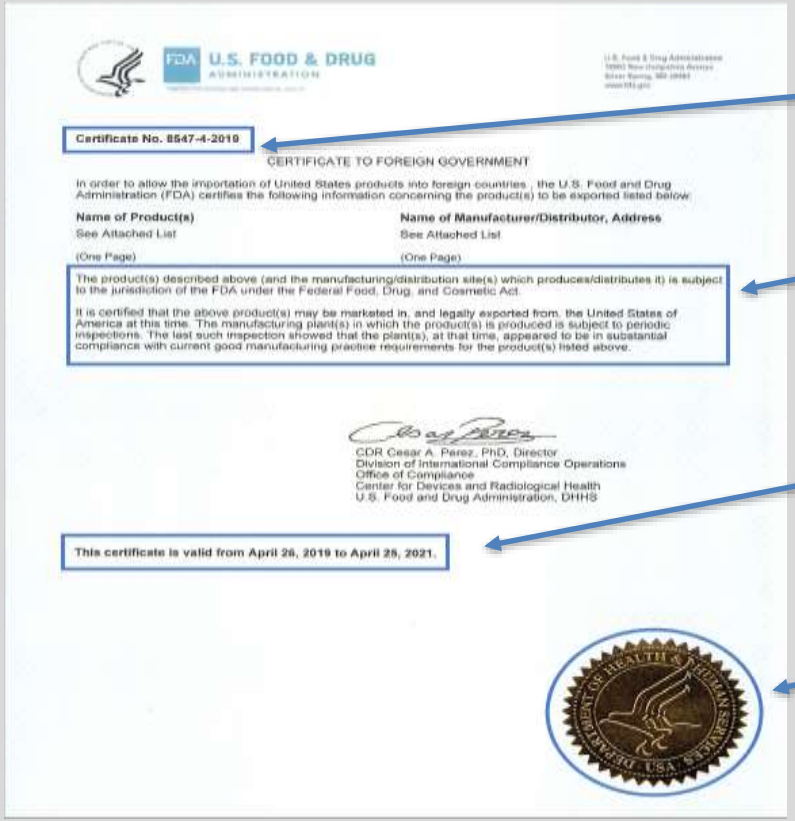
- Requestors must sign a legally binding **exporter's certification statement** (ECS)

- An authorized representative of the **primary facility** must sign the ECS

Who May Apply?

- ONLY for devices that are being **PHYSICALLY** exported from the U.S.
- ONLY requested by a United States-based facility
- Foreign Firms are allowed, but in conjunction with a U.S. Facility

Sample Export Certificate



U.S. FOOD & DRUG ADMINISTRATION

Certificate No. 8547-4-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CDR Cesar A. Perez, PhD, Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from April 26, 2019 to April 25, 2021.

DEPARTMENT OF HEALTH & HUMAN SERVICES USA

Certificate number

Attestation

Valid dates

Raised gold seal

Export Certificates Authentication

- Authentication can be obtained from Department of State
- Certificates may be validated online by using CDRH Export Certificate Validation (CECV) database
  - **Facility name**
  - Certificate type and **number**
  - Number of pages per certificate
  - Expiration date
- Each certificate is valid for 2 years from the date issued

Certificate Options

1. Certificate to Foreign Government (CFG)
2. Certificate of Exportability (COE)
   A. Section 801(e)(1)
   B. Section 802
3. Non-Clinical Research Use Only (NCR)

Document Options

- Simple Notification
- Export Permit Letter

Choosing a Certificate

- Can a device be legally marketed in the U.S.?
- What is the Device Class?

  Product classification database

Certificate Option 1

- **Certificate to Foreign Government (CFG)**
  - Cleared/approved devices for marketing in the U.S. or exempt
  - Class I, II, or III device
  - Establishments are registered and devices are listed with FDA
  - Must meet applicable labeling requirements

Certificate Option 1

- **Certificate to Foreign Government (CFG)**
  - No open recalls
  - Substantial compliance with cGMP
  - Compliance with laws of importing country

Certificate Option 2A

- **Certificate of Exportability (COE) per Section 801(e)(1) of FD&C Act**
  - Not approved for marketing in the U.S.
  - Accords to specification of foreign purchaser
  - Not in conflict with laws of importing country
  - Labeled for “Export Only”

Certificate Option 2A

- **Certificate of Exportability (COE) per Section 801(e)(1) of FD&C Act**
  - Establishments are registered
  - **Likely Class I or II**
  - May be legally exported without a certificate

Certificate Option 2B

- **Certificate of Exportability per Section 802 of FD&C Act**
  - Not approved for marketing in the U.S.
  - Establishments are registered
  - Class III device and associated Class I and II devices
  - **Manufactured according to cGMP (21 CFR 820)**

Certificate Option 2B

- **Certificate of Exportability per Section 802 of FD&C Act**
  - Meet requirements of 801(e)(1)
  - **Marketed or under investigational use in a Tier 1 country**
  - Not adulterated

Tier 1 Countries

- FD&C Act 802(b)(1)(A):
  - Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa
- Member countries of:
  - European Union (EU)
  - European Economic Area (EEA)

Certificate Option 3

- **Non-clinical research (NCR) use only**
  - Export of a product, material, component for non-clinical research use only
  - NOT intended for human use
  - Registration and listing not required
  - Presently offered for sale in the U.S.

Certificate Options Summary

- Certificate to Foreign Government (CFG)
- Certificate of Exportability (COE)
  - Section 801(e)(1)
  - Section 802
- Non-Clinical Research Use Only (NCR)

Document Options

- Simple Notification (SN)
- Export Permit Letter (EPL)

Exporting Unapproved Class III Devices

- Must choose 1:
  - To request certificate of exportability under section 802
  - Provide written notification (Simple Notification)
  - Apply for an Export Permit

Simple Notification

- Exporter must provide written notification to FDA prior to **initial** shipment

- Includes:
  - Type of device
  - Product's trade name and model number
  - Country to receive device

Export Permit

- **Must be obtained prior to export per 801(e)(2) if:**
  - Class III device unapproved
  - **No inspection (cGMP)**
  - Not authorized for use in a Tier 1 country or
  - Not under investigational use in Tier 1 country

Requesting an Export Document

CDRH Export Certification Application and Tracking System (CECATS)

Poll

Have you used CECATS?

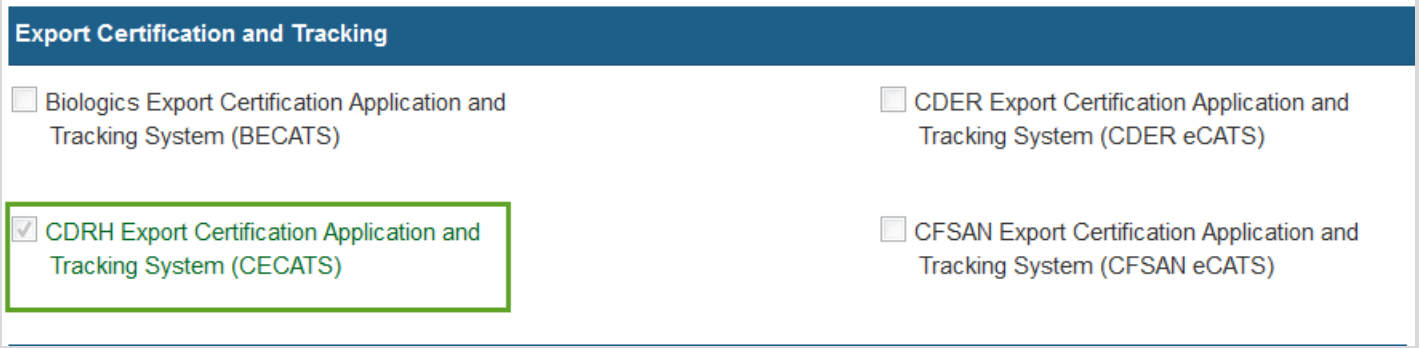
1. Yes
2. No
3. Not sure

CECATS

- Forms automatically selected
- Immediate submission
- Real time updates
- Clone capability

CECATS

- **FDA Unified Registration and Listing System (FURLS)**
  - www.access.fda.gov



Requesting a Certificate

Information needed to apply:

- Name, address and registration numbers
- Marketing status authorization number
- Cleared date
- Recall information

Requesting a Certificate

Needed information:

- Tax ID
- Number of certificates desired
- List of countries
- Date of last inspection if applicable
- Self addressed prepaid return shipping label

Certificate Processing

- Quick turn around
- Returned for action if corrections are needed
  – otherwise certificates are printed and mailed

Cost

- $175 for each original
- $85 for each additional
- No additional cost to list a country on Certificate
- No cost for documents (SN and EPL)

Billing

- Do not include payment with application
- Quarterly

Resources

- U.S. Department of State Office of Authentications
- Food Drug and Cosmetic Act (FD&C) Section VIII
- Record keeping (21 CFR 1.101)

Summary

- **Export Certificates**
  - Approved, cleared or Exempt: CFG
  - Unapproved: COE 801 or 802
  - Non-Clinical
- **Export documents**
  - Simple Notifications
  - Export Permit Letter

Contacts

Email us:

- CECATS: CDRHCECATS@fda.hhs.gov
- Policy: Exportcert@CDRH.fda.gov

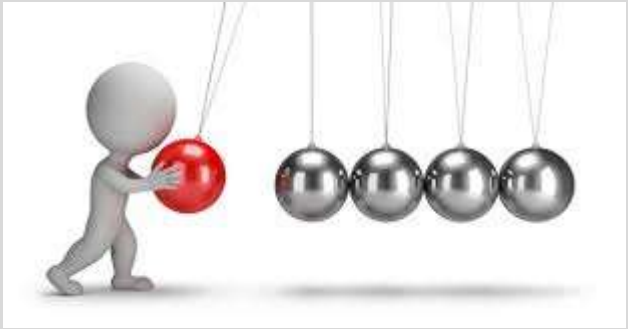
Call us:

- 301-796-7400, Option 3

Questions

Your Call To Action

- Know the marketing status
- Know the device classification
- Become familiar with CECATS

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