# Global Market Innovation with Medical Device Export Certificates

**FDA Small Business Regulatory Education for Industry (REdI) Annual Conference**

May 30, 2024

**Ruth Bediakoh**
Consumer Safety Officer
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration


EXPORT
EXPORT
EXPORT
EXPORT
EXPORT
EXPORT
EXPORT

# Learning Objectives

- Review background information about export certificates
- Identify the types of export certificates issued for medical devices
- Describe conditions for requesting a CFG-NE
- Discuss latest CDRH innovation for export certificates

# Background Information

# Background Information

- An export certificate:
  - A document prepared by the FDA
  - Contains information about a product and/or establishment regulatory or marketing status
  - Certifies in writing that the exported device meets certain specified requirements

# Background Information

- An export certificate:
  - NOT needed to export medical devices
  - Often requested for by foreign governments and customers
- FDA Export Reform and Enhancement Act of 1996 authorized the FDA to:
  - issue certificates
  - charge a fee for issuing certificates

# Background Information

- Authority for exporting medical devices:
  - Section 801(e)(1) and 802 of the FD&C Act
- Prior FDA approval is NOT needed to export medical devices
- Devices that have **not** been approved or cleared in the U.S. must follow the export provisions of the FD&C Act
- Must be labeled that it's intended for export

# Background Information

- Recordkeeping requirements for export under 801(e)(1) & 802 of the FD&C Act
  - 21 CFR 1.101

# Types of Export Certificates

# Type of Export Certificates

- Certificate to Foreign Government (CFG)
- Certificate of Exportability under Section 801(e)(1) (C801)
- Certificate of Exportability under Section 802 (C802)
- Non-Clinical Research Use Only Certificate (NCR)

# Type of Export Certificates

- Certificate to Foreign Government for Devices Not Exported from the United States (CFG-NE)
  - Shipped from a foreign country to another foreign country
  - Requester can be either domestic or foreign establishment

# Knowledge Check

**FDA requires that you obtain export certificates for exporting medical devices.**

1. **True**
2. **False**

# Knowledge Check

**A CFG can be used to export devices from one foreign country to another foreign country.**

1. True
2. False

# Conditions for Requesting a CFG-NE

# Conditions for requesting CFG-NE

| To request a CFG-NE, certify that: |
| --- |
| Device(s) on the certificate is manufactured outside of the U.S.; |
| Establishment(s) on the certificate is currently registered as required by the Act; |
| Each establishment has listed each of the medical devices that appear on the certificate; |
| Device(s) on certificate is authorized to be marketed in the U.S.; |

# Conditions for requesting CFG-NE

| To request a CFG-NE, certify that: |
| --- |
| Device(s) is imported or offered for import into the U.S.; |
| Device(s) identified is not subject of an open import alert, recall, seizure, injunction, or any other open enforcement by the FDA; |
| All establishments involved in the manufacturing process have been identified; |
| Requestor and establishments involved in the manufacturing process comply with cGMP requirements for the identified device. |

# Latest Updates to Export Certificates

# Latest Updates

- Effective January 2, 2024:
  - CDRH ONLY issues export certificates electronically as PDF;
  - Email instructions on how to access and print certificate after approval
  - 45 days to print/download export certificate after issuance;
  - QR Code or URL address for validating each certificate.
    - Certificates may be validated using the FURLS Export Certificate Validator (FECV)

# Latest Updates

U.S. FOOD & DRUG ADMINISTRATION

Certificate No. 1277-6-2024-1

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 |
|---|---|
| Lung sound monitor | See Attached List (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.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from May 07, 2024 to May 06, 2029

To verify the authenticity of the information, go to www.accessfda.gov/fedvlCDRH.

# Latest Updates

# Latest Updates

U.S. FOOD & DRUG ADMINISTRATION

Certificate No. 1277-5-2024-1

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)**

Lung sound monitor

**Name of Manufacturer/Distributor, Address**

See Attached List

(One Page)

The product(s) described above and the manufacturing facilities in which such product(s) is produced are 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 facility in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Tamer, PhD, Director
DRP2, Division of Establishment Support I
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, USA

**This certificate is valid from May 07, 2024 to May 06, 2026.**

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.accessfda.gov/fecs/CD701

# Latest Updates

# Knowledge Check

**Which certificate type can a non-US establishment request from the FDA?**

1. **C801**
2. **CFG-NE**
3. **CFG**

# Resources

| Slide Number | Cited Resource | URL |
|---|---|---|
| 7 | Sec. 801(e)(1) & 802 of FD&C Act | COMPS-973.pdf (govinfo.gov) |
| 8 | 21 CFR 1.101 | www.ecfr.gov/current/title-21/section-1.101 |
| 10 | Types of Export Certificates | www.fda.gov/medical-devices/exporting-medical-devices/types-export-certificates |
| 11 | Devices not Exported from U.S. | www.fda.gov/medical-devices/exporting-medical-devices/devices-not-exported-united-states |

# Summary

- An export certificate is NOT needed to export medical devices, but important to have
- CFG-NE may be requested for devices exported from one foreign country to another if conditions are met
- Export certificates are issued electronically

# Questions

# Your Call to Action

- Review the types of export certificates CDRH issues for medical devices.
- Understand the medical device export provisions under section 801(e)(1) and 802 of the Act.
- Print your electronically issued certificates within 45 days.