

Global Market Innovation with Medical Device Export Certificates

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

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Center for Devices and Radiological Health

U.S. Food and Drug Administration



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



**FDA U.S. FOOD & DRUG
ADMINISTRATION**
DEPARTMENT OF HEALTH & HUMAN SERVICES

U.S. Food & Drug Administration
10925 New Park Drive
Silver Spring, MD 20902
www.fda.gov

Certificate No. 1277-5-2024-1

CERTIFICATE TO FOREIGN GOVERNMENT

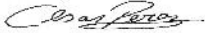
In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

<p>Name of Product(s) Lung sound monitor</p>	<p>Name of Manufacturer/Distributor, Address See Attached List (One Page)</p>
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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, DHH

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.access.fda.gov/ocv/CDRH.

Latest Updates



FURLS EXPORT CERTIFICATE VALIDATOR

Validation of CDRH Export Certificates

To verify the authenticity of a CDRH issued electronic certificate, enter the certificate number and click Submit. You must provide all characters, including hyphens.

Please visit [Online Verification of Export Certificates for Medical Devices](#) and [Exporting Medical Devices Frequently Asked Questions \(FAQs\)](#) for more information.

If the information provided is associated with a valid certificate, the portal will open a copy of the certificate with the watermark **FOR VERIFICATION PURPOSES ONLY**. If an issued certificate has been withdrawn and is no longer valid, the portal will display a copy of the certificate with the watermark **CERTIFICATE WITHDRAWN**.

If there are any inconsistencies between the certificate you received and the certificate provided on this site for verification purposes, please contact CDRHCECATS@fda.hhs.gov.

Certificate Number:

Latest Updates

 **U.S. FOOD & DRUG ADMINISTRATION**
DEPARTMENT OF HEALTH & HUMAN SERVICES

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/distribution sites) which cross(es) border(s) is/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 plant(s) in which the product(s) is produced is/are subject to periodic inspections.

Sincerely,

Peter A. Faner, PhD, Director
DRP2, Division of Established Firm 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, 2026.




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No certificates found matching the search criteria. This could be due to an error in the entered criteria or the certificate has expired.

Certificate Number:

 Submit

 Clear

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.