

Department of Health and Human Services Food and Drug Administration	SUPPLEMENTARY INFORMATION CERTIFICATE FOR DEVICE NOT EXPORTED FROM THE UNITED STATES REQUESTS
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Submit certificate requests and supporting documents to the appropriate Center within FDA that would have control over your device:

CBER: CBER regulates devices involved in the collection, processing, testing, manufacture and administration of blood, blood components and cellular products, and all HIV test kits used both to screen donor blood, blood components, and cellular products and to diagnose, treat, and monitor persons with HIV and AIDS. Please see page 5 for CBER instructions on how to apply for this certificate.

CDRH: CDRH regulates devices ranging from thermometers to kidney dialysis machines and electronic products that emit radiation such as microwaves. Please submit your application online using <https://www.access.fda.gov/oa>. Please see page 6 for CDRH instructions on how to apply for this certificate.

1A. Requestor Information

<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 100%;">Name</td> </tr> <tr> <td>Firm</td> </tr> <tr> <td>Owner operator number (if applicable)</td> </tr> </table>	Name	Firm	Owner operator number (if applicable)	Address
Name				
Firm				
Owner operator number (if applicable)				
Telephone number	Firm Tax ID number (Required for U.S. Requestor)	Email address		
	DUNS number (Required for Requestors outside of the U.S.)			

1B. Billing Address (if not the same as requestor) Alternate Billing Email Address (if not the same as requestor)	1C. Shipping Account Number and/or Label (Mailing supplies may be sent along with this form.)
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2. Manufacturer Information (The following entries are to be entered separately for each firm;

Firm	Address (P.O. Box not acceptable)
Registration number/Firm Establishment Identifier (FEI)	
License number (if applicable)	Date of last FDA inspection or MDSAP audit (must be within 3 years)

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Center for Biologics Evaluation and Research (CBER) instructions begin on page 6.	Center for Devices and Radiological Health (CDRH) instructions are on page 7.
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3. Device Information	
Trade name	Proper name
Marketing application number (BLA/STN, DeNovo, HDE , PMA, 510(k), Preamendment or Exempt – Include number and date approved/cleared/granted if applicable)	Product Code
4. Indicate what device information should appear on the certificate.	
5. Indicate the country destination for which the Certificate(s) is requested. It will be listed on the certificate. CDNE cannot be used to ship device(s) to the United States.	
6. Indicate the total number of certificates requested: _____	

Department of Health and Human Services
Food and Drug Administration

SHIPPER'S CERTIFICATION STATEMENT
"CERTIFICATE FOR DEVICE NOT EXPORTED FROM
THE UNITED STATES"
for CBER

NAME OF MANUFACTURER

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that:

1. Each facility that appears on the certificate is currently registered.
2. Each device identified herein is authorized to be marketed within the United States and is:
 - a. the subject of a premarket notification under section 510(k) of the Federal Food, Drug, & Cosmetic Act (FD&C Act); or
 - b. a device that was in commercial distribution before May 28,1976; or
 - c. exempt from section 510(k) of the FD&C Act; or
 - d. the subject of an approved premarket approval application under section 515(d) of the FD&C Act; or
 - e. the subject of an approved biologics license application under section 351 of the Public Health Service Act; or
 - f. granted De Novo request under section 513(f)(2) of the FD&C Act; or
 - g. approved humanitarian device exemption under section 520(m) of the FD&C Act.
3. Each device identified is identical to the device as indicated in number 2 above, and there have been no modifications to the technology, intended use, indications for use, or labeling;
4. The requesting facility (a) has been inspected by FDA within the past 3 years of the date of this request or (b) audited pursuant to an FDA-recognized program or a program in which FDA participates, and the findings of such audit have been provided to FDA within the past 3 years from the date of this request;
5. Each device identified is not in interstate commerce/commercial distribution in the United States and is not exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submitting of false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years of imprisonment.

SIGNATURE

DATE

NAME AND TITLE

SHIPPER'S CERTIFICATION STATEMENT
"CERTIFICATE FOR DEVICE NOT EXPORTED FROM
THE UNITED STATES"
for CDRH

NAME OF MANUFACTURER

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that:

1. Each facility that appears on the certificate is currently registered;
2. Each device(s) identified herein is authorized to be marketed within the United States and is:
 - a. the subject of a premarket notification under section 510(k) of the Federal Food, Drug, & Cosmetic Act (FD&C Act); or
 - b. a device that was in commercial distribution before May 28, 1976; or
 - c. exempt from section 510(k) of the FD&C Act; or
 - d. the subject of an approved premarket approval application under section 515(d) of the FD&C Act; or
 - e. granted De Novo request under section 513(f)(2) of the FD&C Act; or
 - f. approved humanitarian device exemption under section 520(m) of the FD&C Act
3. Each device identified is identical to the device as indicated in number 2 above, and there have been no modifications to the technology, intended use, indications for use or labeling;
4. The requesting facility (a) has been inspected by FDA within the past 3 years of the date of this request or (b) audited pursuant to an FDA-recognized program or a program in which FDA participates and the findings of such audit have been provided to FDA within the past 3 years from the date of this request;
5. There are no HIV devices listed on the certificate;
6. Each device(s) identified is not in interstate commerce/commercial distribution in the United States and is not exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years imprisonment.

SIGNATURE

DATE

NAME AND TITLE

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Department of Health and Human Services
Food and Drug Administration
INSTRUCTIONS FOR CERTIFICATE FOR DEVICE NOT
EXPORTED FROM THE UNITED STATES FOREIGN
GOVERNMENT (for CBER)

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| <ol style="list-style-type: none"> 1. Any medical device that may be legally marketed in the United States (U.S.) may be shipped anywhere in the world without prior Food and Drug Administration (FDA) notification or approval. The Certificate for Device Not Exported from the United States (CDNE) can be used for products that have received marketing authorization by the FDA and will be shipped from one foreign country to another without entering U.S. commerce. To qualify for a CDNE, the following requirements must be met: <ol style="list-style-type: none"> a. The requesting establishment must be in compliance with the registration requirements; b. The device must have a cleared Premarket Notification 510(k) or Premarket Approval (PMA), or granted a De Novo classification, or if the device was on the market prior to May 28, 1976 (before the Medical Device Amendments to the FD&C Act), or approved humanitarian device exemption under section 520(m) of the FD&C Act; or exempt from section 510(k) of the FD&C Act; or an approved Biologics License Application under section 351 of the Public Health Service Act. c. The device name must appear on the CDNE as authorized for marketing in the U.S. d. The device must meet the labeling requirements of 21 CFR Part 610, 21 CFR Part 660, 21 CFR Part 801, and 21 CFR Part 809, if applicable; e. The requesting establishment must meet the requirements of section 801(e)(4)(E)(iii)(II) of the FD&C Act. f. In addition, the requestor must comply with the laws of the importing country. 2. The CDNE is limited to Manufacturers. Foreign Distributors or Private label Distributor do not qualify for a CDNE. 3. Country of origin (manufacturer's location) and country of destination will be listed on the certificate. 4. The requestor should be a representative of the requesting establishment by having an account associated with the Owner Operator number of the requesting establishment. 5. A representative of the requesting facility must provide a signed Shipper's Certification Statement. 6. It is the requestor's responsibility to ensure that the information on the certificate is supplied correctly, including spelling. 7. If requested, you will need to show proof that a device was offered for sale prior to May 28, 1976. | <ol style="list-style-type: none"> 8. Request an CDNE by sending the request and supporting documents to: <p style="margin-left: 40px;">Food and Drug Administration
Center for Biologics Evaluation and
Research Office of Compliance and
Biologics Quality Division of Case
Management
10903 New Hampshire Ave.
Building 71, Room G112
Silver Spring, MD 20993-0002</p> 9. If information is omitted in the application by the requestor or if clarification is needed, the requestor will be contacted via email or phone. If the requestor does not supply the necessary information within 48 hours, the request for certificates will be closed and will need to be resubmitted for FDA review. 10. Errors made by FDA during the preparation of export certificates will be corrected at no cost to the applicant within 45 days after issuance. Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted. 11. Please include a return UPS or FedEx shipping label that FDA can use to mail the certificates to you. The shipping label must be trackable and electronically generated. When creating the return shipping label, it must be addressed to you. Please use the following as the sender's address: <p style="margin-left: 40px;">Food and Drug Administration
Center for Biologics Evaluation and
Research Office of Compliance and
Biologics Quality Division of Case
Management
10903 New Hampshire Ave.
Building 71, Room G112
Silver Spring, MD 20993-0002</p> 12. CBER has the authority to charge \$175.00 for the first certificate, \$175.00 for the first duplicate and \$85.00 each for subsequent copies. To streamline billing, invoices are sent at the end of the quarter during which the application was received. 13. Issuance of a CDNE will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate. 14. If you have any questions, please call the Import/Export Team at 240-402- 9155 or by email at CBERBECATS@fda.hhs.gov. |
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Department of Health and Human Services
Food and Drug Administration

INSTRUCTIONS FOR
CERTIFICATE FOR DEVICE NOT EXPORTED FROM THE
UNITED STATES (for CDRH)

<p>1. Any medical device that may be legally marketed in the United States (U.S.) may be shipped anywhere in the world without prior Food and Drug Administration (FDA) notification or approval. The Certificate for Device Not Exported from the United States (CDNE) can be used for devices that have received marketing authorization by the FDA and will be shipped from one foreign country to another without entering U.S. commerce. To qualify for a CDNE, the following requirements must be met:</p> <ul style="list-style-type: none">a. The requesting establishment must be in compliance with the registration requirements;b. The device must have a cleared Premarket Notification 510(k) or Premarket Approval (PMA), or granted a De Novo classification, or if the device was on the market prior to May 28, 1976 (before the Medical Device Amendments to the FD&C Act); or approved humanitarian device exemption under section 520(m) of the FD&C Act; or exempt from section 510(k) of the FD&C Act.c. The device name must appear on the CDNE as authorized for marketing in the U.S.d. The device must meet the labeling requirements of 21 CFR Part 801 and 21 CFR 809, if applicable;e. The requesting establishment must meet the requirements of section 801(e)(4)(E)(iii)(II).f. In addition, the requestor must comply with the laws of the importing country. <p>2. The CDNE is limited to Manufacturers. Foreign Distributors or Private label Distributor do not qualify for a CDNE.</p> <p>3. Country of origin (manufacturer's location) and country of destination will be listed on the certificate.</p> <p>4. The requestor should be a representative of the requesting establishment by having an account associated with the Owner Operator number of the requesting establishment.</p> <ul style="list-style-type: none">5. A representative of the requesting facility must provide a signed Shipper's Certification Statement. <p>6. It is the requestor's responsibility to ensure that the information on the certificate is supplied correctly, including spelling.</p>	<p>7. If requested, you will need to show proof that a device was offered for sale prior to May 28, 1976.</p> <p>8. Request a CDNE using one of the following methods. To facilitate your request, please apply through our electronic system, the CDRH Export Certification Application and Tracking System (CECATS) at https://www.access.fda.gov/oa. If you have any problems, please contact us at CDRHCECATS@fda.hhs.gov. You may also mail the request, but effective October 1, 2016, requestors will be contacted to submit requests through CECATS upon receipt of a paper application or notification.</p> <p>9. If information is omitted in the application by the requestor or if clarification is needed, the requestor will be contacted via email or phone. If the requestor does not supply the necessary information within 48 hours, the request for certificates will be closed and will need to be resubmitted for FDA review.</p> <p>10. Errors made by FDA during the preparation of export certificates will be corrected at no cost to the applicant within 45 days after issuance.</p> <ul style="list-style-type: none">• Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted. <p>11. Please include a return UPS, FedEx, or DHL label that FDA can use to mail the certificates to you. The shipping label must be trackable and electronically generated. When creating the return shipping label, it must be addressed to you. Please use the following as the sender's address:</p> <p style="margin-left: 40px;">Food and Drugs Administration CDRH-Office of Regulatory Programs Exports Team 10903 New Hampshire Avenue Building 66, Room 1423 Silver Spring, MD 20993-0002</p> <p>12. CDRH has the authority to charge \$175.00 for the first certificate and \$85.00 each for the subsequent copies. To streamline billing, invoices are sent at the end of the quarter during which the application was received.</p> <p>13. Issuance of a CDNE will not preclude regulatory action by FDA, if warranted, against devices covered by the Certificate.</p> <p>14. If you have any questions, please call 301 796-7400, option 3, or email exportcert@cdrh.fda.gov.</p>
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”