

Guidelines for Shipping Test Articles from Outside the United States to NAMSA

Listed below is the mandatory information needed to process an international shipment through U.S. Customs. Failure to supply any of the following information on a commercial invoice may result in several days delay or a return shipment.

For your reference, an example of a Commercial Invoice is on the following page. The mandatory information needed to process an international shipment is highlighted on this example. Be sure to include the original Commercial Invoice with the shipment.

The following information is required on a Commercial Invoice:

- Name and Address of the test article manufacturer
- Contact Name, Telephone Number, E-mail address of the person shipping the test article
- A detailed description of the contents of the shipment. State what the test articles are (plastic urinary catheter, contact lenses, titanium hip implant, white resin pellets). It is not acceptable to state “medical devices.”
- Include the quantity in the shipment as well as the value of the test articles
- Medical Device Listing (MDL) or 510K Number. If there is not an MDL or 510K number, state the following on the invoice: These test articles are not marketed in the United States, the MDL or 510K number does not apply.
- FDA Product Code. Products codes can be found at <http://www.fda.gov/cdrh/prodcode.html>
- IOR (Importer of Record). This is the name of the company receiving the shipment. Please state NAMSA.
- FDA Registration Number –if one does not exist, indicate that on the commercial invoice
- IRS Number. This is the EIN (Employer Identification Number). If one does not exist, indicate that on the commercial invoice.
-
- The Disposition of the Test Articles. You must indicate that the test articles will be disposed of after testing has been completed (unless you want them returned to you).
- The following statement must be included when shipping test articles: “The test articles contained in this shipment are for research and testing purposes only. No commercial value, not for resale or for clinical use.”

Commercial Invoice

SHIPPER/EXPORTER:	SHIPPING DATE:
CONSIGNEE NAMSA (ADDRESS WHERE YOU SHIPPING TO) (phone #) (fax#)	NAME/ADDRESS OF MANUFACTURER:
FORWARDING AGENT DHL/UPS/Federal Express/Other	SHIPPER CONTACT NAME/PHONE:

QUANTITY	DETAILED DESCRIPTION OF TEST ARTICLE	VALUE for Customs Only
	<p>FDA Product Code:</p> <p>Medical Device Number (MDL):</p> <p>510K Number: (OR) These test articles are not marketed in the United States; no MDL or 510K exists.</p> <p>IRS Number:</p> <p>FDA Registration Number:</p> <p>Importer on Record (IOR): NAMSA</p> <p>The test articles contained in this shipment are for research and testing purposes only. No commercial value, not for resale, not for clinical use.</p> <p>Final Disposition of Test Articles: The test articles contained in this shipment will be disposed of by the testing facility.</p>	

Shipper Signature: _____

Date: _____