

MEDICAL DEVICES – STATEMENT OF INTENT

MEDICAL DEVICES. Purchasers of the medical device items identified in the Invitation for Bid shall certify and assure in writing that such items(s) will be used or resold only under the conditions specified below:

1. Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, et.seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.
2. It shall also be the responsibility of all purchasers to comply with local, state, or other applicable laws. By signing this form, purchasers certify that such property will be used, resold or transported in conformance with FDA regulations. Any proposed destruction of medical equipment must be coordinated with local health and sanitation officials."
3. The following certificate, to be separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the invitation.

a. I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device items identified below. I also certify that prior to sale or use of such devices I will take necessary steps to assure that such devices are not adulterated or misbranded within the meaning of those terms in the Federal Food, Drug, and Cosmetic Act (21 U.S.C.331, et.seq.).

Invitation for Bids Number: _____
Lot Number(s): _____
Print Name: _____
Title: _____ (License Number Required) _____
Full Address: _____

Telephone No.: _____

Signature Date

b. Recognizing that Federal Law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C.331, et.seq.), I certify that I either (1) will sell or otherwise proffer the medical device items identified below only to the persons described in a. above, or (2) will not use those items for their original or usual intended use, or for the other medical use.

Lot Number(s): _____
Print Name: _____
Title: _____
Full Address: _____

Telephone No.: _____

Signature Date

False or misleading statements may result in a fine of not more than \$10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).

ADDITIONAL SPECIAL CONDITIONS AND SPECIAL INSTRUCTIONS

Special Security Notification

Bidders are warned that the misuse of items to compromise national security and/or to create or disseminate biological warfare agents is illegal. Further, the re-sale and/or exportation of certain technological items to countries subject to trade security controls is prohibited as outlined in the "Export Restriction Notice" referenced in the Other Special Requirements and Conditions below. Bidders may be subject to prosecution if items are used for illegal activity.

Export Restriction Notice

The use, disposition, export and reexport of any property is subject to all applicable U.S. laws and regulations, including the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 USC 2752 et seq.); the Export Administration Act of 1979 (50 U.S.C. 2401); DOE Regulations (10 C.F.R. Part 110); International Traffic in Arms Regulations (22 CFR 120 et seq.); Export Administration Regulations (15 C.F.R. 701 et seq.); Foreign Assets Control Regulations (31 CFR 500 et seq.); and the Espionage Act (37 USC 791 et seq.) which among other things, prohibit: (a) The making of false statement and concealment of any material information regarding the use or disposition, export or reexport of the property; and (b) Any use or disposition, export or reexport of the property which is not authorized in accordance with the provisions of the agreement.

STATEMENT OF INTENT: The Government will not sell this property without an approved Statement of Intent. Where a Statement of Intent is required to complete the transaction, no property will be released or removed until all certificates are filed and the property has been cleared for release. There will be no exceptions or exclusions to the Terms and Conditions of sale. Once it is determined that you are the high bidder, after the sale closing date, the following deadlines apply: You will have **five (5) business days** from the sale closing date to submit a completed Statement of Intent to the GSA Sales Contracting Officer (SCO). If revisions to the Statement of Intent are necessary, you will have an additional **five (5) business days** to make revisions and submit an acceptable Statement of Intent. Buyers who have not submitted an acceptable Statement of Intent within **ten (10) business days** will have their winning bids **terminated** and **liquidated damages** assessed. The liability of the Statement of Intent for completeness, correctness and legibility is that of the Buyer of the property. GSA does not control the amount of time required for approval or the final decision to allow or disallow the release of the property to the individual(s) completing and filing the Statement of Intent

**STATEMENT OF INTENT ON NEXT PAGE MUST BE COMPLETED BY SUCCESSFUL BIDDER
PRIOR TO REMOVAL AND FAXED OR EMAILED TO 415-633-1382 OR
christian.patterson@gsa.gov**