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.

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 adultered 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).