

## FDA CERTIFICATION

**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.311, et seq.)

Item Number(s) \_\_\_\_\_

Print Name \_\_\_\_\_

Title \_\_\_\_\_

Full Address \_\_\_\_\_

\_\_\_\_\_

Telephone Number \_\_\_\_\_

(Sign) \_\_\_\_\_ Date \_\_\_\_\_

**b.** Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C.311, et seq.) I certify that I either will sell or otherwise proffer the medical device item(s) identified below only to the persons described in a...above: I will not use those items for their original or usual intended use or for any other medical use.

Item Number(s) \_\_\_\_\_

Print Name \_\_\_\_\_

Title \_\_\_\_\_

Full Address \_\_\_\_\_

\_\_\_\_\_

Telephone Number \_\_\_\_\_

(Sign) \_\_\_\_\_ Date \_\_\_\_\_

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