FDA CERTIFICATION
Fill out section A or B (A – Medical Facilities / B – Device Resellers)

A. I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the prescribed use of the medical device items identified below. I also certify that prior to sale of 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.) The VME- and PVS- Portascope Video Endoscopy Systems is not FDA 510K approved. This equipment has not been approved for medical use in any country.

Product Number _____Serial Number_____
Print Name _____
Title _____
Full Address _____
_____
Telephone Number _____
(Sign) _____ Date _____

B. 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 of 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.)The VME- and PVS- Portascope Video Endoscopy Systems is not FDA 510K approved. This equipment has not been approved for medical use in any country.

Product Number _____Serial Number_____
Print Name _____
Title _____
Full Address _____
_____
Telephone Number _____
(Sign) _____ Date _____

C. Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (2) 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 or b…as noted above: I will not use those items for their original or usual intended use or for any other medical use. The VME- and PVS- Portascope Video Endoscopy Systems is not FDA 510K approved. This equipment has not been approved for medical use in any country.

Product Number _____Serial Number_____
Print Name _____
Title _____
Full Address _____
_____
Telephone Number _____
(Sign) _____ Date _____