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## **Declaration of Conformity for Medical Devices**

Name and address of manufacturer:

Accutome Ultrasound, Inc 263 Great Valley Parkway Malvern, PA 19355 Tel: 610-889-0200

Tel: 610-889-0200 Fax: 610-889-3233

Name and address of authorized representative:

Emergo Europe P.O. Box 18510 2502 EM The Hague The Netherlands Tel: (31) 70 345 8570

Fax: (31) 70 346 7299

Device trade name:

AccuPach V

General Applicable Directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices (MDD 93/42/EEC)

Harmonized Standards:

EN 60601-1, EN 60601-1-2, EN 1441, IEC 1157

Accutome Ultrasound hereby declares under our sole responsibility that the AccuPach V product meets the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices.

Jeffrey L. Wright

Manager of Engineering, Manufacturing, and QC

Date