# EC Declaration of Conformity for Medical Device

| Doc. No: | DOC-24-3000 | Rev. No.: | 01 | Page 1 of 1 | Effective Date: | 05/07/2019 |
|---|---|---|---|---|---|---|

**Manufacturer:** Accutome, Inc.
(also trading as Accutome Ultrasound, Inc.)

**Address:** 3222 Phoenixville Pike
Malvern, PA 19355
Tel: 610-889-0200
Fax: 610-889-3233

**Authorized Representative:** Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (31) 70 345 8570
Fax: (31) 70 346 7299

**General Applicable Directive:**
- Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices
- (MDD 93/42/EEC), as amended by 2007/47/EC.
- Council Directive 2011/65/EU concerning Restriction of Hazardous Substances

**Harmonized Standards:**
- EN IEC 60601-1
- EN IEC 60601-1-2
- EN 60601-2-37
- EN ISO 14971
- IEC 1157

**Device Name:** AccuPen

**Device Classification:** IIa (MDD Annex IX Rule 10)

**Route to Compliance:** Annex VII coupled with Annex V

**EC Certificate:** No. CE 72349
Notified Body Number 2797

| Description | Part Number |
|---|---|
| **AccuPen** | **24-3000** |

*Accessories:*

| Description | Part Number |
|---|---|
| Battery (2) | 24-5101 |
| Lanyard | 5100-0050 |
| AccuTip Covers | AX9950 |
| Manual (English) | 24-3002 |
| Storage Case with Label | 3000-0330 |
| Warning Card | 24-3003 |
| Warning Card | 24-5108 |
| Screwdriver | 24-5107 |
| USB Key w/ Video | 24-6215 |

Accutome, Inc. hereby declares under our sole responsibility that the Accutome product meets the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

**Signature:** _____

**Date:** 7 May 2019

**Full Name:** Claudia Hill

**Position:** Quality & Regulatory Manager