EC Declaration of Conformity for Medical Device

Doc. No:	DOC-24-8000	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 10993
- EN ISO 14971
- IEC 1157
- EN IEC 62304

Device Name: 4Sight

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
4Sight	**24-8000**

Accessories:

Description	Part Number
A-Scan Probe	24-8000A
Pachymeter Probe	24-8000P
B-Scan Probe	24-8000B
UBM Probe	24-8000U

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

Digitally signed by Grabazei Alexandru
Date: 2023.08.28 11:47:43 EEST
Reason: MoldSign Signature
Location: Moldova