By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 72349**

Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

In respect of:

The manufacture of Ophthalmic Diagnostics Biometers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2003-02-13** Date: **2019-02-20** Expiry Date: **2023-02-12**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 72349**
Date:	**2019-02-20**
Issued To:	**Accutome, Inc.** **also trading as Accutome Ultrasound** **3222 Phoenixville Pike** **Malvern** **Pennsylvania** **19355** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 72349**

Date: **2019-02-20**

Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Date	Reference Number	Action
13 February 2003	4416792	First Issue.
02 July 2003	4460181	Certificate reissued due to change of address.
12 February 2004	4423195	Certificate reissued due to change to company name.
28 January 2008	7162453	Certificate Renewal.
07 May 2008	7204112	Certificate re-issue to reflect address change.
20 October 2009	7444037	Extension to scope to include Sterile Ophthalmic Blades and addition of EU representative as significant sub-contractor. Addition of 'Steris Isomedix Services, New Jersey' as a significant sub-contractor for Gamma Sterilization.
16 September 2010	7534221	Certificate re-issue due to extension to scope from 'Ophthalmic Ultrasound Diagnostics Biometers' to 'Ophthalmic Diagnostics Biometers'.
28 January 2013	7915335	Certificate Renewal.
13 July 2015	8359679	Scope reduced by removal of "and Sterile Ophthalmic Blades" and removal of significant subcontractor Steris Isomedix Services Inc.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 72349**

Date: **2019-02-20**

Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Date	Reference Number	Action
29 March 2018	8868299	Certificate Renewal. Change of Emergo Europe's address from Molenstraat 15, 2513 BH The Hague, Netherlands to Prinsessegracht 20, 2514 AP The Hague, Netherlands.
Current	7781700	Traceable to NB 0086.