Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 11.11.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) **4Sight** 24-8000
2) **A-Scan Probe** 24-8000A
3) **Pachymeter Probe** 24-8000P
4) **B-Scan Probe** 24-8000B
5) **UBM Probe** 24-8000U

Se anexează următoarele acte:
1) Declarație de Conformitate, nr. DOC-24-8000 Rev. No.: 01 din 05/07/2019
2) Certificarte CE no. CE 72349
3) Certificarte extindere perioada valabilitate CE no. US-MF-000036181
4) Actul prin care producătorul își desemnează reprezentantul

Data 11.11.2023 Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.11.11 12:11:46 EET
Reason: MoldSign Signature
Location: Moldova

Către
Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. ”DataControl” S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscînd prevederile art. **352[1]** , Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1) **4Sight** 24-8000
2) **A-Scan Probe** 24-8000A
3) **Pachymeter Probe** 24-8000P
4) **B-Scan Probe** 24-8000B
5) **UBM Probe** 24-8000U

Se anexează următoarele acte:
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3) Certificarte extindere perioada valabilitate CE no. US-MF-000036181
4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității

Alexandru Grabazei, director Semnătura _____

Data: **11.11.2023**

Date: 29 August 2023

Windsor, UK

Authorisation Letter

To Whom It May Concern
Herewith we, Keeler Ltd, who are established and reputable manufacturer of Ophthalmic Products and accessories having factories at Windsor, UK, SL4 4AA, Clewer Hill Road, authorize the company.

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of medical devices manufactured by us.
Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose the above company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, to conduct any field actions which may be necessary in accordance with legislation of Republic of Moldova.

Registration certificates must be issued in the name of Keeler Ltd.
This authorisation letter is valid for a period of 12 (twelve) months from the date of issue.

Signed: DocuSigned by: Arminder Purewal 03365BA1DB9E428... Date: 29 Aug 2023

Name: Arminder Purewal
Title: Head of Global Regulatory Affairs & EMEA Quality Assurance

+44 1753 857177 | info@keeler.co.uk | Clewer Hill Road, Windsor, SL4 4AA, United Kingdom | keeler.co.uk

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

Accutome, Inc.
DBA Keeler USA
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

7 July 2023

Notified Body Confirmation Letter
Reference: EU2023-607/ 652523

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Accutome Inc., DBA Keeler USA.
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA
SRN Number: US-MF-000036181

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Digitally signed by
Mingxiang Xu
Date: 2023.07.07
17:13:38 -04'00

Mingxiang Xu

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4Sight	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
Accupen	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
PachPen	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
A Scan Plus Connect	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
B Scan Plus	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
UBM Plus Guarded	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
Accutips Cover	Class IIa	N/A	CE 72349, Exp 12 Feb 2023, NB 2797
Device 8	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 9	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 10	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	Choose an item.	N/A	N/A
Device 2	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 3	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 4	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 5	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 6	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 7	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 8	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Notified Body certificate under Directives
Device 9	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 10	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2023/07/07	Initial issue

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.