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 **06.09.2023**

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, 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:

Keeler:

1. KSL-Z, model: 3020-P-2041

Se anexează următoarele acte:
1. Declarație de Conformitate No. DOC-24-800 – din 05/07/2019
2. Certificatul de conformitate CE – Nr. CE 72349 din 20/02/2019
3. Certificatul ISO 13485 No. FM 701460 din 07/02/2023

Data **06.09.2023** 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: 2023.11.27 09:27:05 EET
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md,

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

Keeler:

1. KSL-Z, model:3020-P-2041;

Sunt autentice și corespund realității.

Grabazei Alexandru, director general *Semnătura* _____

Data **06.09.2023**

Keeler Ltd
Clewer Hill Road
Windsor
Berkshire
SL4 4AA
UNITED KINGDOM

21 Apr 2023

Subject: Justification for Extension of CE Certifications issued under the Medical Device Directive 93/42/EEC (MDD).

As you may be aware, The European Parliament has voted to adopt an extension of the transition period for the EU Medical Device Regulations and to extend the validity of the current MDD EC Certifications.

MDR deadlines have now been extended based upon the risk class of the Medical Device(s) as indicated in the Extension Letter supplied by our Notified Body SGS (See supporting Extension Letter).

We, Keeler Ltd (the Legal Manufacturer) hereby declare that as per Medical Device Directive 93/42/EEC, our EC Certifications are deemed valid and permits us to continue placing our Medical Devices on the market which remain compliant under the Medical Devices Directive (MDD) in accordance with the Extension Letter.

CE certifications we currently hold are as follows:

EC Certification	EC Certification Number	Expiry Date	Extended Expiry
SGS EC Annex II Certificate (excl. Section 4)	GB20 965236	23 Mar 2023	31 Dec 2028
SGS EC Annex V Certificate	GB20/965237	23 Mar 2023	31 Dec 2028

As the Legal Manufacturer I can also confirm the following:
1) There have been no significant changes in the design and purpose of the medical device(s);

2) The medical device(s) do not pose an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of health care.

Yours faithfully,

DocuSigned by:
Signed: _____ Date: 21/04/2023
03365BA1DB9E428...

Arminder Purewal
Head of Global Regulatory Affairs & EMEA Quality Assurance
Keeler Ltd

Keeler Ltd
Clewer Hill Road
Windsor, Berkshire
SL4 4AA, UK

27/03/2023

Confirmation Letter Reference: CLNB1639 CL-0005

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

Keeler Ltd
Clewer Hill Road
Windsor, Berkshire
SL4 4AA, UK
SRN Number: GB-MF-000009031

Visiometrics, S.L
Vinyals, 131
08221, Terrassa
Spain

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 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 the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / 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
Applanation Tonometer to aid diagnosis and measurement of intraocular pressure / 50552727ATONOMETER8Y	Class I devices placed on the market in measuring condition	N/A	GB20/965237; NB1639
Disposable Applanation Tonometer Cone for use in	Class I devices placed on the market in	N/A	GB20/965237; NB1639

Device name / 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
testing of intraocular pressure /50552727TONOCLEARR7	sterile condition		
Disposable Cryo Probe for use with Ophthalmic Surgery Devices / 50552727CRYOPROBESJ9	Class IIa	N/A	GB20/965237; NB1639
Keeler Cryomatic MKII Console & Pencils for use in ophthalmic Surgery / 50552727CRYOCONSOLEBT (Cryo Console MKII) and 50552727CRYOPROBESJ9 (Probes)	Class IIb	N/A	GB20/965236; NB1639
Laser Indirect Ophthalmoscope (LIO) for use in ophthalmic surgical procedures / 50552727LINDOSCOPE67	Class IIb	N/A	GB20/965236; NB1639
Pulsair Intellipuff - Non-Contact Tonometer / 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Pulsair Desktop Tonometer/ 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Tonocare – Non- Contact Tonometer / 50552727TONOCARE8H	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT) / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT), Z-Type / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
27.03.2023	Version 1	Initial issue

EC Declaration of Conformity to:
Medical Device Regulation (MDR) 2017/745

Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
SRN:	GB-MF-000009031
Manufacturing Site(s):	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
EU Authorised Representative:	Visiometrics, S.L., Vinyals, 131 08221 Terrassa, Spain
SRN:	ES-AR-000001559
Swiss Authorised Representative:	Medicel AG Dornierstrasse 11 CH-9423 Altenrhein Switzerland
Device Description/Family:	Keeler Slit Lamps (See attached Product Schedule)
Basic UDI-DI:	50552727SLITLAMPSRG
EC Product Classification:	Class I -Self certified, Annex VIII, Rule 10 under MDR 2017/745
EC Conformity Assessment:	Annex II and III Technical Documentation + Annex IV Declaration of Conformity
Intended Purpose	The Desktop Slit Lamp is an AC-powered slit lamp biomicroscope that is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is also used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segment. The lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment of the human eye, which includes the eyelid, sclera, conjunctiva, iris, natural crystalline lens and cornea. The examination with a binocular slit lamp gives a stereoscopic enlarged image of the eye structures in detail, enabling the health practitioner to make an anatomical diagnosis for a variety of eye conditions.
GMDN Code:	35148 – Ophthalmic slit lamp, examination An electrically-powered, ophthalmic, binocular microscope designed to examine the interior anatomy of the eye (anterior and posterior surfaces) by viewing through the iris. It produces a narrow slit of powerful light which is projected into the eye, and resulting light reflections are detected obliquely with a travelling microscope to enable observation of the internal ocular surfaces. It is used to perform a variety of measurements [e.g., intraocular pressure (IOP) or tonometry, corneal thickness, anterior chamber depth] and to evaluate symptoms (e.g., eye itchiness, grittiness, pain, dry eyes, photophobia, and reduced visual acuity).
EMDN Code:	Z12120108 – Slit lamps

We herewith declare, as the sole manufacturer, that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Medical Device Regulation (MDR) 2017/745 of 5 April 2017 as amended, concerning medical devices and the applicable union legislation identified below.

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Applied Directives:	• Medical Device Regulation (MDR) - EU 2017/745 • Unique Device Identification (UDI) - 2013/172/EU • Restriction of Hazardous Substance (RoHS) 3 – 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive – 2012/19/EU • MEDDEV 2.7/1 Rev. 4
Applied Standards:	• BS EN ISO 13485:2016+A11:2021 • BS EN ISO 14971:2019+A11:2021 • BS EN ISO 10993-1:2020 • BS EN 60601-1:2006+A2:2021 • BS EN 60601-1-2:2015/A1:2021 • BS EN 62133-2:2017+A1:2021 • BS EN 62304:2006 +A1:2015 • BS EN ISO 10939:2017 • BS EN 60601-1-6:2010 +A2:2021 • BS EN 62366-1:2015 + A1:2020 • BS EN ISO 15004-1:2020 • BS EN ISO 15004-2:2007 • BS EN ISO 15223-1:2021 • BS EN ISO 20417:2021 • BS EN ISO 14155:2020 • BS EN 50419:2006 • BS EN 62471:2008
Notified Body:	***SGS Belgium NV (NB# 1639)*** SGS House, Noorderlaan – 87, Antwerp, 2030 – Belgium +32 3 545 44 00 https://www.sgs.be/en/

DofC Reference to Tech File: DofC 02 **Rev:** 26

Signed:  **Date:** 11 May 2023

Name: Arminder Purewal

Head of Global Regulatory & EMEA Quality Assurance, Keeler Ltd.

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Product Schedule:

GMDN 35148			
Part Number	**Product Description**	**Product Classification**	**GTIN**
3020-P-2006	SLH 5XC LED REF	I	05055272711593
3020-P-2006-001	SLH 5XC LED REF STD - CHINA	I	05055272719476
3020-P-2007	SLH 5XC LED TBL	I	05055272711586
3020-P-2007-001	SLH 5XC LED - LARGE TABLE	I	05055272718394
3020-P-2009	SLH 5XC LED Di REF ST	I	05055272715164
3020-P-2010	SLH 5XC LED Di TBL	I	05055272715171
3020-P-2013	SLH 5XC LED TBL USA	I	05055272711784
3020-P-2015	SLH 5XC LED Di TBL USA	I	05055272715195
3020-P-2019	SLH 5XC LED DiR REF	I	05055272715201
3020-P-2020	SLH 5XC LED DiR TBL	I	05055272715218
3020-P-2021	SLH 5XC LED DiR TBL USA	I	05055272715225
3020-P-2023	SLZ 3XP REF	I	05055272715232
3020-P-2023-003	SLZ 3XP REF (WHITE)	I	05055272718479
3020-P-2024	SLZ 3XP TBL	I	05055272715249
3020-P-2025	SLZ 3XP TBL USA	I	05055272715256
3020-P-2026	SLZ 3XP Di REF	I	05055272715263
3020-P-2027	SLZ 3XP Di TBL	I	05055272715270
3020-P-2028	SLZ 3XP Di TBL USA	I	05055272715287
3020-P-2029	SLZ 3XP DiR REF	I	05055272715294
3020-P-2030	SLZ 3XP DiR TBL	I	05055272715300
3020-P-2031	SLZ 3XP DiR TBL USA	I	05055272715317
3020-P-2032	SLZ 5XP REF	I	05055272715324
3020-P-2033	SLZ 5XP TBL	I	05055272715331
3020-P-2034	SLZ 5XP TBL USA	I	05055272715348
3020-P-2035	SLZ 5XP DI REF	I	05055272715355
3020-P-2036	SLZ 5XP Di TBL	I	05055272715362
3020-P-2037	SLZ 5XP Di TBL USA	I	05055272715379
3020-P-2038	SLZ 5XP DiR REF	I	05055272715386
3020-P-2039	SLZ 5XP DiR TBL	I	05055272715393
3020-P-2040	SLZ 5XP DiR TBL USA	I	05055272715409
3020-P-2041	SLZ 3XC REF	I	05055272715416
3020-P-2042	SLZ 3XC TBL	I	05055272715423
3020-P-2043	SLZ 3XC TBL USA	I	05055272715430
3020-P-2044	SLZ 3XC Di REF	I	05055272715447
3020-P-2045	SLZ 3XC Di TBL	I	05055272715454
3020-P-2046	SLZ 3XC Di TBL USA	I	05055272715461
3020-P-2047	SLZ 3XC DiR REF	I	05055272715478
3020-P-2048	SLZ 3XC DiR TBL	I	05055272715485
3020-P-2049	SLZ 3XC DiR TBL USA	I	05055272715492
3020-P-2050	SLZ 5XC REF	I	05055272715508
3020-P-2051	SLZ 5XC TBL	I	05055272715515
3020-P-2052	SLZ 5XC TBL USA	I	05055272715522
3020-P-2053	SLZ 5XC Di REF	I	05055272715539
3020-P-2054	SLZ 5XC Di TBL	I	05055272715546
3020-P-2055	SLZ 5XC Di TBL USA	I	05055272715553
3020-P-2056	SLZ 5XC DiR REF	I	05055272715560
3020-P-2057	SLZ 5XC DiR TBL	I	05055272715577

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GMDN 35148			
Part Number	**Product Description**	**Product Classification**	**GTIN**
3020-P-2058	SLZ 5XC DiR TBL USA	I	05055272715584
3020-P-2059	SLH 5XC LED TBL VALON	I	05055272715591
3020-P-2070	SLH 5XC LED REF OEM	I	05055272715645
3020-P-2077	SLZ 3XC REF WHT	I	05055272716857
3020-P-2078	SLZ 3XC TBL WHT	I	05055272716864
3020-P-2079	SLZ 5XC REF WHT	I	05055272716871
3020-P-2080	SLZ 5XC TBL WHT	I	05055272716826
3020-P-2081	SLH 5XC LED - PLATE SYSTEM	I	05055272717236
3020-P-2082	SLH 5XC LED Di - PLATE SYSTEM	I	05055272718257
3020-P-2083	SLH 5XC LED DiR - PLATE SYSTEM	I	05055272718264
3020-P-2084	SLZ 5XC LED - PLATE SYSTEM	I	05055272718271
3020-P-2085	SLZ 5XC LED Di - PLATE SYSTEM	I	05055272718288
3020-P-2086	SLZ 5XC LED DiR - PLATE SYSTEM	I	05055272718295
3020-P-2089	SLH 3XC LED - REF	I	05055272717113
3020-P-2090	SLH 3XC LED - TABLE	I	05055272717120
3020-P-2091	SLH 3XC LED TABLE USA	I	05055272718097
3020-P-2092	SLH 3XC LED Di - REF	I	05055272717137
3020-P-2093	SLH 3XC LED Di - TABLE	I	05055272717144
3020-P-2094	SLH 3XC LED Di TABLE USA	I	05055272718103
3020-P-2095	SLH 3XC LED DiR - REF	I	05055272717151
3020-P-2096	SLH 3XC LED DiR - TABLE	I	05055272717168
3020-P-2097	SLH 3XC LED DiR TABLE USA	I	05055272718110
3020-P-2098	SLH 3XP LED - REF	I	05055272717175
3020-P-2099	SLH 3XP LED - TABLE	I	05055272717182
3020-P-2101	SLH 3XP LED Di - REF	I	05055272717199
3020-P-2102	SLH 3XP LED Di - TABLE	I	05055272717205
3020-P-2104	SLH 3XP LED DiR - REF	I	05055272717212
3020-P-2105	SLH 3XP LED DiR - TABLE	I	05055272717229
3020-P-2108	SLZ 5XC Di REF - WHITE	I	05055272717298
3020-P-2109	SLZ 5XC Di TBL - WHITE	I	05055272719681
3020-P-2110	SLZ 5XP Di REF - WHITE	I	05055272720410
3020-P-2112	SLH 5XP LED Di REF (WHITE)	I	05055272718066
3020-P-2113	SLH 5XC LED REF (WHITE)	I	05055272718073
3020-P-2114	SLH 5XC LED TABLE (WHITE)	I	05055272718080
3020-P-2121	SLZ 5XP REF WHITE	I	05055272718950
3020-P-2123	SLZ 5XP DiR REF WHITE	I	05055272718967
3020-P-2124	SLZ 3XP Di REF WHITE	I	05055272719377
3020-P-2125	SLZ 5XC LED PLT SYS - WHITE	I	05055272718882
3020-P-2126	SLH 3XP LED REF WHITE	I	05055272719384
3020-P-2127	SLH 5XP LED REF GREY	I	05055272719193
3020-P-2128	SLH 5XP LED REF WHITE	I	05055272719391
3020-P-2129	SLH 3XP LED DiR REF WHITE	I	05055272719407
3020-P-2130	SLH 5XP LED DiR REF	I	05055272719414
3020-P-2131	SLH 5XP LED DiR REF WHITE	I	05055272719261
3020-P-2132	SLH 3XP LED Di REF WHITE	I	05055272719421
3020-P-2133	SLH 5XP LED Di REF	I	05055272719124
3020-P-2135	SLH 5XC LED - PLATE SYSTEM (WHITE)	I	05055272719278
3020-P-2136	SLZ 5XC DiR REF (WHITE)	I	05055272719483
3020-P-2137	SLZ 5XC DiR TABLE (WHITE)	I	05055272719490

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GMDN 35148			
Part Number	**Product Description**	**Product Classification**	**GTIN**
3020-P-2138	SLH 5XC LED Di PLATE SYSTEM (WHITE)	I	05055272719506
3020-P-2139	SLH 3XC LED - PLATE SYSTEM	I	05055272719544
3020-P-2140	SLH 3XC LED Di - PLATE SYSTEM	I	05055272719636
3020-P-2141	SLH 3XC LED DiR - PLATE SYSTEM	I	05055272719643
3020-P-2142	SLZ 3XC LED - PLATE SYSTEM	I	05055272719551
3020-P-2143	SLZ 3XC LED DiR - PLATE SYSTEM	I	05055272719650
3020-P-2144	SLZ 3XC LED Di - PLATE SYSTEM	I	05055272719667
3020-P-2145	SL-B2 3XC SLIT LAMP	I	05055272720090
3020-P-2145-001	SL-B2 3XC SLIT LAMP	I	05055272720137
3020-P-2145-002	SL-B2 3XC SLIT LAMP	I	05055272720144
3020-P-2146	NIDEK SLH 5XC LED - PLATE SYSTEM	I	05055272720588
3020-P-2151	SLH 5XC LED DiR - PLATE SYSTEM (WHITE)	I	05055272720281
3020-P-2155-002	SL-B3 3XC SLIT LAMP (GEN)	I	05055272720199
3020-P-2160	MODULIGHT SLIT LAMP	I	05055272720298

Accessories			
Part Number	**Product Description**	**Product Classification**	**GTIN**
1030-P-7160	BULB	Accessory	05055272700580
1205-P-7012	KAPTURE SOFTWARE MEMORY STICK	Accessory	05055272718240
2199-P-7136	LENS CLOTH	Accessory	05055272705516
2207-P-1026	2x HALBERG TRIAL CLIPS IN CASE	Accessory	05055272706520
3020-P-2022	DSL DIGITAL CAMERA KIT	Accessory	05055272711692
3020-P-2147	KSL DIGITAL KONNECT CAMERA KIT	Accessory	05055272720656
3020-P-5007	BASE ASSEMBLY (TABLE-TOP VARIANT ONLY)	Accessory	05055272715676
3020-P-5031	DSL DIGITAL CAMERA ASSEMBLY	Accessory	05055272715683
3020-P-5036	CHINREST ASSEMBLY	Accessory	05055272715690
3020-P-5041	DSL TABLE ASSEMBLY - DIGITAL	Accessory	05055272715706
3020-P-5062	DSL TABLE ASSY - USA REFRACTION STAND	Accessory	05055272715737
3020-P-5063	DSL DIGITAL USA REFRACTION STAND ASSEMBLY	Accessory	05055272720076
3020-P-5121	12V PSU & DRAWER KIT	Accessory	05055272715782
3020-P-5131	DSL CAMERA ASSEMBLY - NO BRANDING	Accessory	05055272719612
3020-P-5151	SL CHINREST ASSEMBLY - PLT SYS	Accessory	05055272717250
3020-P-5179	SLH/SLZ LARGE TABLE TOP ASSEMBLY	Accessory	05055272718400
3020-P-5191	SLH PLATE SYSTEM CHINREST ASSY	Accessory	05055272719452
3020-P-5211	OCULUS/KEELER T/T ASSEMBLY - 12V	Accessory	05055272719032
3020-P-5332	SLITLAMP CAMERA - MODULIGHT	Accessory	05055272720649
3020-P-7000	MULTI VOLTAGE TABLE LEG ASSEMBLY	Accessory	05055272715812
3020-P-7007	MAINS CABLES – BRAZIL	Accessory	05055272715843
3020-P-7008	MAINS CABLES - JAPAN	Accessory	05055272715850
3020-P-7011	POWER SUPPLY TO SLIT LAMP BASE CABLE (TABLE-TOP VARIANT ONLY)	Accessory	05055272715874
3020-P-7013	DSL REFRACTION CABLE (XY - BULB)	Accessory	05055272715898
3020-P-7016	MAINS CABLES - NORTH AMERICA	Accessory	05055272715911
3020-P-7017	REFRACTION STAND PSU & SKT KIT	Accessory	05055272715928

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Accessories			
Part Number	**Product Description**	**Product Classification**	**GTIN**
3020-P-7020	LED REFRACTION STAND ACCESSORY KIT	Accessory	05055272715935
3020-P-7020-003	SLH LED REF ACCESSORY KIT - WHITE	Accessory	05055272719292
3020-P-7021	LED TABLE TOP ACCESSORY KIT	Accessory	05055272715942
3020-P-7021-003	SLH LED TABLE ACCESSORY KIT (WHITE)	Accessory	05055272719438
3020-P-7026	DSL DIGITAL TABLE ACCESSORY KIT	Accessory	05055272715966
3020-P-7032	SLIT LAMP USA REFR STAND KIT	Accessory	05055272715973
3020-P-7036	KEELER KAPTURE LITE LICENCE	Accessory	05055272720526
3020-P-7037	KAPTURE VIDEO LICENCE	Accessory	05055272720533
3020-P-7038	KEELER KAPTURE DIGITAL LICENCE	Accessory	05055272720540
3020-P-7039	KEELER KAPTURE DIGITAL PRO LICENCE	Accessory	05055272720557
3020-P-7042	UPGRADE KAPTURE LITE TO DIGITAL SOFTWARE	Accessory	05055272718011
3020-P-7045	KAPTURE VIEW SOFTWARE	Accessory	05055272718028
3020-P-7046	KAPTURE VIEW PLUS SOFTWARE	Accessory	05055272718035
3020-P-7051	DSL DIGITAL LED REFRACTION STAND ACCESSORY KIT	Accessory	05055272715997
3020-P-7051-003	SLH LED Di REF ACCESSORY KIT - WHITE	Accessory	05055272718318
3020-P-7052	TABLE ACCESSORY KIT DIGITAL	Accessory	05055272716000
3020-P-7055	Z-TYPE DSL REFRACTION STAND ACCESSORY KIT	Accessory	05055272716239
3020-P-7055-003	Z-TYPE REFRACTION STAND ACCESSORY KIT	Accessory	05055272716918
3020-P-7056	Z-TYPE DSL TABLE TOP ACCESSORY KIT	Accessory	05055272716109
3020-P-7056-003	Z-TYPE TABLE TOP ACCESSORY KIT	Accessory	05055272716833
3020-P-7057	Z-TYPE DSL DIGITAL REFRACTION STAND ACCESSORY KIT	Accessory	05055272716246
3020-P-7057-003	SLZ Di REF STD ACCESSORY KIT - WHITE	Accessory	05055272717274
3020-P-7058	Z-TYPE DSL DIGITAL TABLE TOP ACCESSORY KIT	Accessory	05055272716253
3020-P-7058-003	SLZ Di TBL TOP ACCESSORY KIT - WHITE	Accessory	05055272717281
3020-P-7061	DIELECTRIC PROJECTION MIRROR KIT	Accessory	05055272716024
3020-P-7065	OEM ACCESSORY KIT	Accessory	05055272716055
3020-P-7070	VALON ACCESSORY KIT 1	Accessory	05055272716086
3020-P-7081	SLH/SLZ MOUNTING PLATE SYSTEM	Accessory	05055272717243
3020-P-7082	DSL/ZSL LARGE TABLE IN CARTON	Accessory	05055272716932
3020-P-7084	QUANTEL DSL ACCESSORY KIT	Accessory	05055272716819
3020-P-7086	SL CHINREST & MOUNTING PLATE SYSTEM	Accessory	05055272719285
3020-P-7100	SLH CHINREST MOUNTING PLATE SYSTEM	Accessory	05055272719254
3020-P-7105	EYEPIECE WITH RETICULE	Accessory	05055272719308
3020-P-7115	LUMENIS SLIT LAMP CAMERA - WHITE	Accessory	05055272720168
3020-P-7126	NIDEK SLH ACCESSORY KIT	Accessory	05055272720595
3020-P-7145	KEELER KONNECT IMAGING SOFTWARE (INSTALL PROGRAMME USB + LICENCE USB KEY)	Accessory	05055272720618
3020-P-7150	KSL KL (P) TABLETOP & LEG KIT	Accessory	05055272720632
3020-P-7151	KEELER KONNECT PACs LICENSE (LICENSE USB)	Accessory	05055272720625
3104-L-8201	CHIN REST PAPERS	Accessory	05055272708074
EP39-80273	DUST COVER	Accessory	05055272712255

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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**

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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**

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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.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: FM 701460

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The distribution of ophthalmic knives. The distribution and service of ophthalmic instruments. The design, development, manufacture, distribution and service of ophthalmic ultrasound diagnostic devices and handheld applanation tonometers.

Previous certificate expires on 2023-02-04
Recertification audit ended 2023-01-04

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2003-02-13
Latest Revision Date: 2023-02-07

Effective Date: 2023-02-07
Expiry Date: 2026-02-04

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