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,

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

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