EC Certificate Full Quality Assurance System: Certificate GB19/964798

The management system of

Idoman Teoranta

Killateeaun, Tourmakeady, County Mayo, Ireland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Thermablate – Endometrial Ablation System:
Control Unit and Disposable Cartridge.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 17 May 2021 until 27 April 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 27 April 2011.

Certification is based on reports numbered GB/PC 222996

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Corrigendum to Certificate GB19/964798

Idoman Teoranta

Killateeaun, Tourmakeady, County Mayo, Ireland

Scope:

Thermablate – Endometrial Ablation System: Control Unit and Disposable Cartridge.

This corrigendum is only valid together with accompanying 93/42/EEC certificate Issue 2

Correction date	Correction
Change approved by SGS on 12 July 2023	Addition of Postcode - F12 C6H0

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

SGS Belgium NV
Certification and Business Enhancement Maatschappelijke Zetel/Siège
Noorderlaan 87 B-2030 Antwerpen/Anvers
t +32 (0)3 545 48 48 f +32 (0)3 545 48 49
www.be.sgs.com

Idoman Teoranta
Killateeaun
Tourmakeady,
County Mayo F12 Pk75
Ireland

02/05/2023

Confirmation Letter Reference: CLNB1639 GBPC 222996

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:

Idoman Teoranta
Killateeaun
Tourmakeady,
County Mayo F12 Pk75
Ireland

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
Thermablate – Endometrial Ablation System: Control Unit and Disposable Cartridge UDI-DI 53920000741EASNN	Class IIb	N/A	GB19/964798; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/02	Version 1	Initial issue

SGS Belgium NV

Certification and Business Enhancement Registered Office: Noorderlaan 87 BE-2030 Antwerpen t +32 (0)3 545 48 48 f +32 (0)3 545 48 49
Boulevard International/Internationalelaan 55D BE-1070 Brussels t+32 (0)2 556 00 40 f +32 (0)3 545 48 49 www.be.sgs.com

Member of the SGS Group

RPR Antwerpen VAT BE 0404 882 750 Belfius 550-3560000-93