

Medical Device Full Quality Assurance System Certificate GB23/00000295

SGS

The management system of

Idoman Teoranta

Killateeoun, Tourmakeady, County Mayo, F12 C6H0, Ireland

has been assessed and certified as meeting the requirements of
Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

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 Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/222996

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 08 April 2026 until 08 April 2031 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 25 July 2023



Authorised by

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Head of Approved Body

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