EU Quality Management System Certificate GB26/00000193

The management system of

Idoman Teoranta

Killateeaun Tourmakeady County Mayo F12 C6HO Ireland
SRN Number: IE-MF000000090

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 05 November 2026 until 05 November 2031 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 05 May 2031

Issue 1. Certified since 05 November 2026

Authorised by
Virginie Siloret
Head of Certification and Compliance

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EU Quality Management System Certificate
GB26/00000193, continued

Idoman Teoranta

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIb devices:
MDA 0303, MDS 1005, MDS 1009
EMDN: Z12080201

Thermablate EAS Thermal Balloon Endometrial Ablation System:
Thermablate EAS Treatment Control Unit Kit comprising of Treatment Control Unit and accessories - Basic UDI-DI 53920000741TCURB
Sterile and Single-Use Thermablate EAS Disposable Cartridge, packed in Acrylic Tube or PETG Tray - Basic UDI-DI 53920000741EASNN

Intended Purpose: A thermal ablation system intended to ablate the endometrial lining of the uterus in women suffering from excessive uterine bleeding due to benign causes for whom childbearing is complete.

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - GB/PC/222996 - S2A 1.3 + TFR 1.5
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

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