Medical Device Full Quality Assurance System Certificate GB23/00000295

The management system of



Idoman Teoranta

Killateeaun 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 25 July 2023 until 25 July 2028 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 25 July 2023

2. Henderson

Authorised by Lynn Henderson

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