EC Certificate Full Quality Assurance System: Certificate GB11/82944

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 12 May 2017 until 27 April 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 January 2020
Issue 5. Certified since 27 April 2011

Certification is based on reports numbered GB/PC 222996

Authorised by

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