

Certificate GB20/965763

The quality management system of

# Idoman Teoranta



Killateeoun Tourmakeady County Mayo F12 C6H0 Ireland

has been assessed and certified as meeting the requirements of

## **MDSAP (ISO 13485:2016)**

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1

For the following activities

Design, manufacture and distribution of treatment control unit and disposable cartridge for endometrial ablation.

Manufacture of disposable surgical instrument kits for sonohysterography and tubal patency assessment.

Manufacture of sterile disposable wing needles for delivery of local anaesthetic to the uterine cavity.

This certificate is valid from Effective date 2024-03-28 until Expiry date 2026-04-27 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2020-04-29



Authorised by

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