EC Certificate Full Quality Assurance System: Certificate GB12/86323

The management system of

Gaeltec Devices Ltd

Glendale Road, Dunvegan, Isle of Skye, Scotland, IV55 8GU, UK

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

Medical pressure transducers.

Class I Measuring: Metrological aspects only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

Data Logger (Cuillin NanoLogger CH2-CH9) for the recording of Non-vital physiological parameters.

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 30 October 2015 until 29 October 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 October 2018
Issue 4. Certified since 01 July 1998

Certification is based on reports numbered GB/PC 229429

Authorised by

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