

The management system of

Digitimer Ltd

37 Hydeway, Welwyn Garden City,
Hertfordshire, AL7 3BE, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4) & Annex V

For the following products

Annex II (excluding Section 4)

Percutaneous, cortical and spinal stimulators including D185, D185-Mk.IIa, DS7A, DS7AH and DS5. Isolated patient amplifiers including D360.

Annex V

Sterile and non-sterile urological investigation catheters. Sterile pump infusion sets and manometer lines.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 14 October 2011 until 14 October 2016 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 14 October 2014

Issue 11. Certified since 07 March 1997

Certification is based on reports numbered GB/PC 07415

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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