EC Certificate Full Quality Assurance System: Certificate GB19/964554

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)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 18 November 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 07 March 1997.

Certification is based on reports numbered GB/PC 07415

Authorised by

Global Medical Devices Head of Notified Body

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Digitimer Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Multipulse cortical and spinal stimulators (D185 and D185-Mk.IIa) for intraoperative monitoring of motor evoked potentials (MEPs) during spinal neurosurgery or procedures that require aortic clamping.

Percutaneous, bipolar (DS5) and high voltage constant current (DS7A, DS7AH, DS7AP) stimulators intended for use during neurological monitoring, assessment and diagnosis in a clinical environment.

Isolated patient biological amplifiers (D360) for use in clinical diagnostic situations for studies of EMG, EEG and Evoked Potentials (EP).

Medical pressure transducers.

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.