

EC Certificate Full Quality Assurance System: Certificate US13/82920

The management system of

RhythmLink International LLC

1140 1st Street South,
Columbia, SC, 29209, United States

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

Subdermal Electrodes for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals in the area of Electromyography (EMG), Electroencephalograph (EEG) and Nerve potential signals. Mono, Ball Tip and Concentric Probes for spinal fusion or pedicle screw testing, or nerve location, muscle or nerve stimulation during surgery. Neurosurgical Procedure Kit used for EMG, muscle or nerve stimulation and location during robotic surgery.

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 23 April 2014 until 24 July 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 June 2016

Issue 2. Certified since 24 July 2013

Certification is based on reports numbered WW/ME 604839

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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