EC Certificate Full Quality Assurance System: Certificate US19/819943607

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 March 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 24 July 2013
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MW 604839

Authorised by

SGS Belgium NV, Notified Body 1639
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Rhythmlink International LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Subdermal Electrodes for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals in the area of Electromyography (EMG), Electroencephagraph (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.

Class 1 Sterile: Sterility Aspects Only – Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. Sterile alligator clips, electrode cable for use in the recording of Intraoperative Neurophysiological Monitoring as an accessory for general surgical instrumentation.

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.