EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Alpha Omega Engineering Ltd.

Nazareth Industrial Park Building
Mount Precipice
Nazareth 1612102
Israel

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Physiological Navigation system for Neurosurgery:
NeuroNav Drive - Class IIb
NeuroNav - Class IIb
Sterile Single Use MER Cable Accessory – Class Is
NeuroOmega Drive – Class IIb
NeuroOmega System – Class IIb
NeuroProbe (Sterile and Non-Sterile) – Class III
NeuroSmart – Class IIb
Disposable Cannulas for neurosurgery (Sterile and Non-Sterile) – Class III

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	071157 MR2
Certificate unique ID	170690716
Effective date	2017-09-11
Expiry date	2021-12-30
Frankfurt am Main	2017-09-11

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.