EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Sequent Medical Inc.

11A Columbia
Aliso Viejo, CA 92656
United States of America

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:

Medical devices for the treatment of intravascular diseases according to annex.

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.	456350 MR2
Certificate unique ID	170705029
Effective date	2018-03-01
Expiry date	2023-02-28
Frankfurt am Main	2018-02-02

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 456350 MR2
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Device family	Device	Class
Aneurysm Embolization Device	WEB™ Aneurysmen Embolization System Detachment Control Device	III IIa
Microcatheter	VIA™ Microcatheter	III