



## **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 Managing Director Dr. Thomas Feldmann Head of Certification Body

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Annex to certificate

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Device family	Device	Class
Aneurysm Embolization Device	WEB™ Aneurysmen Embolization System Detachment Control Device	III Ila
Microcatheter	VIA™ Microcatheter	Ш

