



# EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

## Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way  
Irvine, CA 92618  
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:

Implants for Interventional Minimal Invasive Therapy 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.	281863 MR2
Certificate unique ID	170582950
Effective date	2013-12-03
Expiry date	2018-12-02
Frankfurt am Main	2013-11-18

## DQS Medizinprodukte GmbH

Frank Graichen  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

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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.



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Device family	Device	Class
Aneurysm Embolization Device	LUNA™ Aneurysm Embolization System	III
Axium™ Detachable Coil System	Axium™ Helix	III
	Axium™ 3D	III
	Axium™ Nylon Helix	III
	Axium™ PGLA Helix	III
	Axium™ PGLA 3D	III
Axium™ Prime Detachable Coil System	Axium™ Prime Bare Platinum Helix	III
	Axium™ Prime Bare Platinum 3D	III
	Axium™ Prime MicroFX PGLA Helix	III
	Axium™ Prime MicroFX PGLA 3D	III
	Axium™ Prime MicroFX Nylon Helix	III
Concerto™ Detachable Coil System	Concerto™ Bare Platinum Helix	III
	Concerto™ Bare Platinum 3D	III
	Concerto™ PGLA Fiber Helix	III
	Concerto™ PGLA Fiber 3D	III
	Concerto™ Nylon Fiber Helix	III
Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
	Pipeline™ Embolization Device	III
Detachment Devices	Sapphire Detachment System (SDS)	IIa
	Detachment System (NDS-1)	IIa
	Solitaire™ NDS-2 Detachment System	IIa
	Sapphire Cable Set sterile (SCS), Cable Set sterile (NCS), Solitaire Cable Set (CSS), Instant Detacher (I.D.) for the Axium™ Detachable Coils, Instant Detacher (I.D.) for Axium™ Prime Detachable Coils	Is
Revascularization Device	Solitaire™ FR Revascularization Device	III
	Solitaire™ 2 Revascularization Device	III

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Device family	Device	Class
Liquid Embolic Systems	Onyx® Liquid Embolic System	III
Surgical Instruments for Circulatory System	Alligator™ Retrieval Device – Neurovascular and Peripheral Application	III
Infusion Catheters	Cragg McNamara™ Catheter	IIb
	MicroMewi™ Infusion Catheter	IIb
Infusion Wires	ProStream™ Infusion Wire	IIb
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III
	HyperForm™ Occlusion Balloon System	III
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Introducer Sheath	IIb
	Onyx™ Syringe Catheter Interface Adapter	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	Silverspeed™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	X-Celerator™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III

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Device family	Device	Class
Flow Directed Catheter	Marathon Flow Directed Micro Catheter	III
	Ultraflow™ HPC Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter System	Navien™ A+Intracranial Catheter	III

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