



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

MicroVention Europe

30 bis, rue du Vieil Abrevoir
78100 Saint-Germain-en-Laye
France

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:

Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Catheter, Microspheres and EPC – Embolic Protection System as listed in 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.	487703 MR2
Certificate unique ID	170638471
Effective date	2015-12-30
Expiry date	2018-12-26
Frankfurt am Main	2015-12-22

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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



Annex to Certificate

Certificate registration No.: 487703 MR2

Certificate unique ID: 170638471

Effective date: 2015-12-30

MicroVention Europe

30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France

Production Sites:

- 1 MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America
- 2 MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela
Costa Rica

Distribution Site:

MicroVention, Inc.
1800 E. Wilshire Ave.
Santa Ana, CA 92705
United States of America

Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS Intraluminal Support Device	III	1, 2
	LVIS Jr. Intraluminal Support Device		
	FRED® Flow Re-Direction Endoluminal Devices	III	1,2
	FRED Jr.® Flow Re-Direction Endoluminal Devices		
CASPERS™ RX Carotid Artery Stent System	Roadsaver™ Carotid Artery Stent System	III	1,2
Clot Retriever	ERIC™ Retrieval Device	III	1
Liquid Embolic System	PHIL™ Liquid Embolic System	III	1
Catheter	SOFIA™ Distal Access Catheter	III	1,2
	SOFIA™ PLUS Catheter		
	SOFIA™ Guiding Catheter		
Microspheres	HydroPearl Microspheres LifePearl Microspheres	IIb	1



Annex to Certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170638471
Effective date: 2015-12-30



MicroVention Europe

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Device Groups:	Devices:	Risk Class	Production Site
EPC – Embolic Protection Device	Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1