EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

that the design of the following device(s)

Scepter C™ Occlusion Balloon Catheter
Scepter XC™ Occlusion Balloon Catheter
Scepter Mini™ Occlusion Balloon Catheter

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 411133 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: ST18-0008C - Technical Design Dossier For The Scepter Occlusion Balloon Catheters, April 2019 dated 2019-09-25

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_Scepter_R2020_V1 dated 2020-02-03

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	494215 MRA
Certificate unique ID	170763222
Effective date	2020-02-03
Expiry date	2024-05-26
Frankfurt am Main	2020-02-03

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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.

CERTIFICATE

This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	411133 MP2016
Certificate unique ID	170758666
Effective date	2019-11-17
Expiry date	2022-11-16
Frankfurt am Main	2019-11-17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 411133 MP2016
Certificate unique ID: 170758666
Effective date: 2019-11-17

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Location	Scope
MicroVention, Inc. **Production Site** 35 Enterprise Aliso Viejo, CA, 92656 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention, Inc. **Production Site** 1311 Valencia Ave. Tustin, CA, 92780 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention Costa Rica, S.R.L. **Production Site** Zona Franca Coyol Alajuela Costa Rica	Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
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:

Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires) and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units 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.	411133 MR2
Certificate unique ID	170752398
Effective date	2019-10-07
Expiry date	2022-11-02
Frankfurt am Main	2019-10-07

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America

2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela,
Costa Rica

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical – Standard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 & 3D - Complex 10 & 18 - Compass 10 & 18, - COSMOS® 10 & 18 - VFC™	III	1,2,3
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, - HydroSoft® 10 - HydroFill® - HydroFrame® 10 & 18 - HydroSoft 3D	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35 AZUR® HydroCoil Pushable Embolization Coils 18 & 35 AZUR® Framing Detachable Coils 18 & 35 AZUR® Injectable Coil System 18 & 35 AZUR Detachable 18 AZUR PURE Pushable Coil System 18 & 35 AZUR CX Detachable 18 & 35	IIb	1,2,3
Detachment Controller Units		V-Grip® Detachment Controller V-Grip® PLUS Detachment Controller WEB Detachment Controller AZUR® Detachment Controller	IIa IIa IIa IIa	1,2 1,2 1,2 1,2
Intravascular Access Devices		Traxcess® 14 Guidewire Traxcess® 14 EX Guidewire Traxcess® 14 SELECT Guidewire Traxcess® 7 Mini Guidewire Traxcess® 7 Mini XSoft Guidewire Traxcess® Docking Wire	III IIa	2 2

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Catheters		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter		2,3
		Headway® 17 Advanced Microcatheter		2,3
		Headway® 21 Microcatheter		2,3
		Headway® 27 Microcatheter		2,3
		Headway Duo Microcatheter		2,3
		Scepter C™ Occlusion Balloon Catheter		1,2,3
		Scepter XC™ Occlusion Balloon Catheter		1,2,3
		Scepter Mini™ Occlusion Balloon Catheter		1,2
		SOFIA™ Distal Access Catheter		1,2,3
		SOFIA™ Select Catheter		1,2,3
		SOFIA™ PLUS Catheter		1,2,3
		SOFIA™ Flow PLUS Catheter		1,2,3
		SOFIA™ Guiding Catheter		1,2,3
		SOFIA™ Flow Catheter		1,2,3
		SOFIA® EX Catheter		1,2,3
		KANSHAS Drug Coated Balloon		1
		VIA™ 17 Microcatheter		2
		VIA™ 21 Microcatheter		2
		VIA™ 27 Microcatheter		2
		VIA™ 33 Microcatheter		2
		Wedge Microcatheter		2,3
Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		LVIS Jr.™ Intraluminal Support Device		
		LVIS™ EVO Intraluminal Support Device		
		FRED® Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.® Flow Re-Direction Endoluminal Device		1,2,3
		CASPER™ RX Carotid Artery Stent System		1,2,3
		Roadsaver Carotid Artery Stent System		1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Peripheral Vascular Stent System		CASPER™ Peripheral Vascular Stent System	IIb	1,2,3
		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System Microspheres		PHIL™ Liquid Embolic System	III	1,2
		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1,2
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,2,3
		Nanoparasol Embolic Protection System		
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Tubing Kit		Aspiration Tubing Kit	Is	2
Aspiration Syringe Kit		Aspiration Syringe Kit	Is	2
AZUR Vascular Plug		AZUR Vascular Plug	IIb	1,2
PG Pro Microcatheter		PG Pro Microcatheter	IIa	1,2

EC DECLARATION OF CONFORMITY

RF18-0182, Rev. B

We, MicroVention, Inc., located in Tustin, California, USA, declare according to Directive 93/42/EEC Annex II (excl. Section 4.) under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Directives: 93/42/EEC Council Directive Concerning Medical Devices

Conformity Assessment Route:
EC Design Examination: 494215 MRA
Full Quality Assurance: 411133 MR2

Product	Model Number(s)	Class-Rule	GMDN Code
Scepter XC Occlusion Balloon	**BC0411XC**	III – Annex 9, rule 8	32584
Scepter C Occlusion Balloon	**BC0410C** **BC0415C** **BC0420C**		
Scepter Mini Occlusion Balloon	**BC0210M**		

Manufacturer	Notified Body	European Representative
MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention Europe** 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France

Intended Use: For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms. For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter Occlusion Balloon Catheter.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

J. Kulinets

Irina Kulinets
SVP Regulatory, Quality and Clinical
MicroVention, Inc.

Tustin, CA 92780, USA
Place of Issue

5/30/2019
Date of Issue

DC19-02670

MicroVention Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
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Scepter
Occlusion Balloon Catheter

Occlusion Balloon Catheters

The New Standard of Excellence, Redefining Deliverability, Versatility, and Control

Scepter C™ Compliant Balloon Catheter

Product Code	Description	Balloon Diameter (mm)	Balloon Length (mm)	Distal Tip Length (mm)
1 balloon catheter, 1 introducer sheath, 1 shaping mandrel per box				
BC0410C	Compliant Occlusion Balloon 4.0mm x 10mm	4.0	10	5
BC0415C	Compliant Occlusion Balloon 4.0mm x 15mm	4.0	15	5
BC0420C	Compliant Occlusion Balloon 4.0mm x 20mm	4.0	20	5

Scepter XC™ X-tra Compliant Balloon Catheter

Product Code	Description	Balloon Diameter (mm)	Balloon Length (mm)	Distal Tip Length (mm)
1 balloon catheter, 1 introducer sheath, 1 shaping mandrel per box				
BC0411XC	X-tra Compliant Occlusion Balloon 4.0mm x 11mm	4.0	11	5

Features	Benefits
14 Wire Compatible	Provides more choices of guidewire (Traxcess® docking wire compatible) Improves trackability and stability with better performance of the wire
Hydrophilic Coating on the Balloon	Significantly improves trackability Enables use of longer balloons without compromising trackability
Soft & Long Tip	Improves balloon stability and trackability
Low Profile	Ensures compatibility with double catheter technique in 6F guide Improves trackability
Distal Tip Marker	Positive identification of distal tip location

MicroVention® TERUMO

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MM228(i) Rev.C 1/13