EC DECLARATION OF CONFORMITY

FD08-001, Rev. R

We, MicroVention, Inc., located in Tustin, California, USA declare according to Directive 93/42/EEC Annex II (incl. 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: 411133 MRA (Section 4)
Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Traxcess 14 Guidewire*	GW1420040	III – Annex IX, Rule 7, Subclause 1	2018-05-27	35094
Traxcess 14EX Guidewire*	GW1420040X			
Traxcess 14 SELECT Guidewire	GW1420040S			
Traxcess 7 Mini	GW0721006M			
Traxcess 7 Mini XSoft	GW0721006S			
Traxcess Docking Wire*	GW14100EX	IIa- Annex IX, Rule 7		61281

Manufacturer/ Production Site:
MicroVention Inc,
1311 Valencia Avenue
Tustin, CA 92780 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

EU Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Ashitaka Factory of Terumo Corp. *
150 Maimaigi-Cho
Fujinomiya, Sizuoka Japan

Intended Use: The Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

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.

Sal Palomares
Regulatory Affairs Director
MicroVention, Inc.

Tustin, CA 92780, USA — Place of Issue

28 June 2018 — Date of Issue

Expiry Date: 2023-05-26
Prepared for Romania

Digitally signed by Grabazei Alexandru
Date: 2022.08.08 15:06:10 EEST
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

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

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

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.

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

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

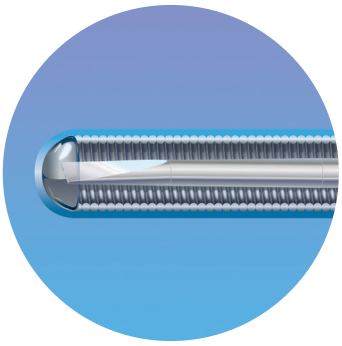
Traxcess®
Guidewire

Control, Durability, and Versatility—All in One.

Traxcess® Guidewire, the first neuro-guidewire with hybrid nitinol/stainless steel technology, is uniquely designed to reach challenging distal anatomies. It combines exceptional tip softness and flexibility with precise torque response, to help you get to your destination.

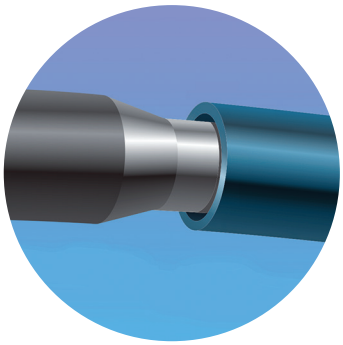
Control

- Hybrid nitinol/stainless steel construction offers a soft, atraumatic tip while maximizing push/pull control and torque response*
- Lubricious hydrophilic coating allows smooth advancement of the guidewire within the vasculature and microcatheter*
- Excellent tip shapability and shape retention design promotes controlled steerability*



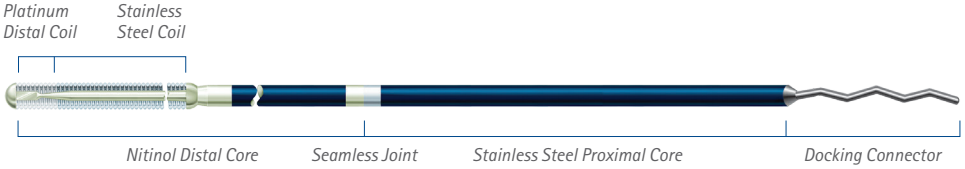
Durability

- Proprietary hydrophilic coating offers exceptional integrity and durability*
- Kink-resistant distal nitinol core maintains its shape throughout the procedure, even through the most tortuous vessels*



Versatility

- Innovative Traxcess® Docking Wire simplifies catheter exchange, intra-procedurally, reducing time and cost



MicroVention® TERUMO

Traxcess® Guidewire

Traxcess® 14 Guidewire

Product Name	Description	Product Code	Total Length	Hydrophilic Coating Length	Radiopaque Tip Length	Distal OD	Proximal OD
Traxcess® 14	Soft	GW1420040	200 cm	40 cm	3 cm	0.012 in (0.30 mm)	0.014 in (0.36 mm)
Traxcess® 14 SELECT	Soft	GW1420040S	200 cm	97 cm	3 cm	0.012 in (0.30 mm)	0.014 in (0.36 mm)
Traxcess® 14 EX	Support	GW1420040X	200 cm	40 cm	6 cm	0.012 in (0.30 mm)	0.014 in (0.36 mm)

Straight, shapeable tip. Shapeable tip length: 1.4 cm.
Packed 1 guidewire per box. Includes shaping mandrel, insertion tool, and torque device.

Added features of the new Traxcess® 14 SELECT Guidewire

- Distal 3 cm tip redesigned for improved support and better vessel selectivity
- Longer hydrophilic coating for enhanced overall navigation and reduced friction with compatible catheters
- Optimized accessories: longer wire shaping mandrel, torque device with improved grip, and longer introducer

Traxcess® Docking Wire

Product Name	Product Code	Total Length	Outer Diameter
Traxcess® Docking Wire	GW14100EX	115 cm	0.014 in (0.36 mm)

Packed 1 docking wire per box.

- Traxcess® Docking Wire extends the length of Traxcess® 14 Guidewires into exchange length (313 cm) without the need for removing the guidewire, which is then easily returned to the original 200 cm by removing the docking wire

For more information or a product demonstration, contact your local MicroVention representative.

MicroVention TERUMO

INDICATIONS FOR USE:
The Traxcess® 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. The device is not intended for use in coronary arteries. There are no known contraindications. Refer to Instructions for Use for additional information.

MM549 (EMEA) Rev. A 11/16

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