EC DECLARATION OF CONFORMITY

RF18-0060 Rev. D

DC Number: DC20-06187

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, declare according to Directive 93/42/EEC Annex II 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.

Council Directive 93/42/EEC

Conformity Assessment Procedure Performed:

EC Design Examination Certificate ☒ (Annex II.4) 514729 MRA (Section 4) **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 (Excluding Section 4) **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
Roadsaver™ Carotid Artery Stent	See Page 2	III – Annex 9, Rule 8	45851

Legal Manufacturer	Production Site(s)		Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA 35 Enterprise Aliso Viejo, CA 92656 USA	MicroVention, Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.

Docusigned by:
Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 9/21/2020 | 7:33:51 PM PDT
F47F956B62B5424CBF023EA37BA8F01F

Irina Kulinets Sr. Vice President, Regulatory Affairs, Quality, Clinical Research MicroVention Europe SARL	Saint-Germain-en-Laye, France Place of Issue	9/21/2020 Date of Issue

Certificate Expiry Date: 2024-05-26

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper – 78100 Saint-Germain-en-Laye
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 - E-mail : contact-europe@microvention.com

EC DECLARATION OF CONFORMITY

RF18-0060 Rev. D
DC Number: DC20-02605

Roadsaver™ Carotid Artery Stent Model Numbers:

Model Number	Stent Implant Unconstrained Dimensions	
	Outer Diameter (mm)	Overall / Dual Layer Length (mm)
RDS-0520-143RX	5	25 / 20
RDS-0530-143RX	5	37 / 30
RDS-0540-143RX	5	47 / 40
RDS-0616-143RX	6	22 / 16
RDS-0625-143RX	6	33 / 25
RDS-0630-143RX	6	40 / 30
RDS-0718-143RX	7	25 / 18
RDS-0725-143RX	7	35 / 25
RDS-0730-143RX	7	40 / 30
RDS-0820-143RX	8	25 / 20
RDS-0825-143RX	8	35 / 25
RDS-0830-143RX	8	40 / 30
RDS-0840-143RX	8	47 / 40
RDS-0920-143RX	9	33 / 20
RDS-0930-143RX	9	40 / 30
RDS-1020-143RX	10	35 / 20
RDS-1030-143RX	10	43 / 30

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Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 - E-mail : contact-europe@microvention.com

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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:

Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Catheters, Embolic Protection System, Aneurysm Embolization Devices and Microspheres 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	170776103
Effective date	2021-04-29
Expiry date	2024-05-26
Frankfurt am Main	2021-04-29

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170776103
Effective date: 2021-04-29

MicroVention Europe SARL

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

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.: 487703 MR2
Certificate unique ID: 170776103
Effective date: 2021-04-29

MicroVention Europe SARL

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

Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS™ Intraluminal Support Device	III	1,2,3
	LVIS™ Jr. Intraluminal Support Device	III	1,2,3
	LVIS™ EVO™ Intraluminal Support Device	III	1,2,3
	LVIS™ X™ Intraluminal Support Device	III	1,2,3
	LVIS™ Jr. X™ Intraluminal Support Device	III	1,2,3
	LVIS™ EVO™ X™ Intraluminal Support Device	III	1,2,3
	FRED™ Flow Re-Direction Endoluminal Devices FRED Jr. ™ Flow Re-Direction Endoluminal Devices FRED X™ Flow Re-Direction Endoluminal Devices FRED OMEGA™ Flow Re-Direction Endoluminal Devices	III	1,2,3
	CASPER™ RX Carotid Artery Stent System	III	1,2,3
	Roadsaver™ Carotid Artery Stent System	III	1,2,3
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	PHIL™ Liquid Embolic System	III	1,2
Catheter	SOFIA™ Distal Access Catheter	III	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

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170776103
Effective date: 2021-04-29

MicroVention Europe SARL

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

Device Groups:	Devices:	Risk Class	Production Site
Microspheres	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
Detachment Controller Units	WEB Detachment Controller	IIa	1,2
Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	IIa	1,2

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe SARL

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

that the design of the following device(s)

CASPER™ Carotid Stent System / Roadsaver™ Carotid Stent System
CASPER™ X Carotid Stent System / Roadsaver™ X Carotid Stent System

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. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: ST18-0003 Casper Roadsaver STED.pdf dated 2019-08-23
ST18-0003 Rev. C_CASPER Roadsaver STED_19MAR2021.docx dated 2021-03-18

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

Examination report: 411_18e_Report_TFR_CASPER_Roadsaver.docx dated 2020-04-21
411_18e_Report_TFR_CASPER_X_Roadsaver_X_V2.docx dated 2021-04-08

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

Certificate registration no.	514729 MRA
Certificate unique ID	170775599
Effective date	2021-04-08
Expiry date	2024-05-26
Frankfurt am Main	2021-04-08

DQS Medizinprodukte GmbH

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Managing Director

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Head of Certification Body

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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 Europe SARL

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

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

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device and Microspheres.

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.	487703 MP2016
Certificate unique ID	170781087
Effective date	2022-11-14
Expiry date	2025-11-13
Frankfurt am Main	2022-10-17

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

DQS IS A MEMBER OF IQNET

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Tel. +49 (0) 69 95427-300, info-med@dqs.de
The validity of this certificate can only be verified by the QR-code.