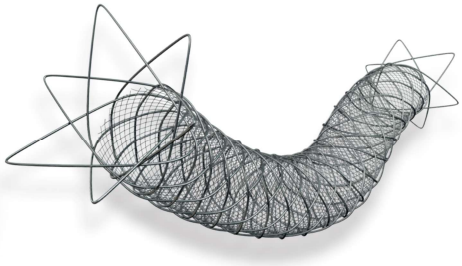
Roadsaver®

Carotid Artery Stent

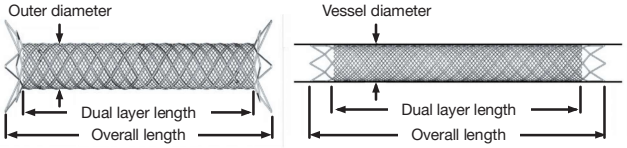


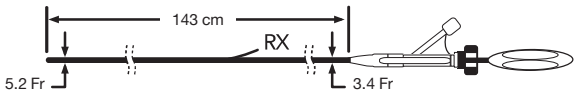
The Roadsaver® Carotid Stent System is indicated for use in patients with carotid arterial atherosclerotic disease.

Product Characteristics

A novel design - Nickel titanium (Nitinol) double layer micromesh design

- ***Provides excellent wall apposition***
- ***Superior in-vessel flexibility***
- ***Allows for side branch patency***
- ***Conforms to tortuous anatomies***
- ***In-Vivo tapering of braided Nitinol design conforms to tapered ICA-CCA segments Sustained embolic protection***
- ***Designed to prevent plaque protrusion and emboli release after stent implantation***
- ***Double-layer micromesh designed to contain plaque to the vessel wall***





Specifications

Stent platform

Construction	Double layer, braided mesh
Material	Nitinol

Stent delivery system

Guidewire compatibility	0.014" (0.36 mm)
Introducer sheath compatibility	5 Fr (I.D. > 0.074'")
Delivery system construction	Rapid exchange, RX segment length 25 cm
Usable catheter length	143 cm

Ordering Informations

Product code	Unconstrained dimensions (mm)			Implanted dimensions (mm)					
				Vessel Ø 1mm smaller than unconstrained Ø			Vessel Ø 2mm smaller than unconstrained Ø		
	Stent diameter	Micromesh layer stent length	Overall stent length	Vessel diameter	Micromesh layer length	Overall length	Vessel diameter	Micromesh layer length	Overall length
RDS-0520-143RX	5	20	25	4	20	33	3	22	35
RDS-0530-143RX	5	30	37	4	35	47	3	38	52
RDS-0540-143RX	5	40	47	4	45	59	3	52	64
RDS-0616-143RX	6	16	22	5	20	32	4	23	35
RDS-0625-143RX	6	25	33	5	30	44	4	33	48
RDS-0630-143RX	6	30	40	5	40	53	4	43	58
RDS-0718-143RX	7	18	25	6	23	35	5	26	38
RDS-0725-143RX	7	25	35	6	30	47	5	36	52
RDS-0730-143RX	7	30	40	6	40	53	5	44	60
RDS-0820-143RX	8	20	25	7	25	36	6	27	40
RDS-0825-143RX	8	25	35	7	30	49	6	38	54
RDS-0830-143RX	8	30	40	7	40	55	6	45	61
RDS-0840-143RX	8	40	47	7	50	67	6	60	75
RDS-0920-143RX	9	20	33	8	30	45	7	33	48
RDS-0930-143RX	9	30	40	8	40	55	7	45	60
RDS-1020-143RX	10	20	35	9	30	45	8	35	50
RDS-1030-143RX	10	30	43	9	40	55	8	45	60

Please quote above item reference code when placing an order

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE
I.3. Certificatul CE	Certificate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		roadsaver								
DM000186836	Stent vascular, carotida	ROADSAVER™	RDS -1020-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186827	Stent vascular, carotida	ROADSAVER™	RDS -0718-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186837	Stent vascular, carotida	ROADSAVER™	RDS -1030-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186830	Stent vascular, carotida	ROADSAVER™	RDS -0820-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186829	Stent vascular, carotida	ROADSAVER™	RDS -0730-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186823	Stent vascular, carotida	ROADSAVER™	RDS -0540-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186832	Stent vascular, carotida	ROADSAVER™	RDS -0830-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186828	Stent vascular, carotida	ROADSAVER™	ROS -0725-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186821	Stent vascular, carotida	ROADSAVER™	RDS -0520-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186825	Stent vascular, carotida	ROADSAVER™	RDS -0625-143RX		Franta	MICROVENTION EUROPE S.A.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	

Страница 1 из 2 (Всего элементов: 17) 1 2

Содержит([NameMake], 'roadsaver')

Очис

MicroVention TERUMO

EC DECLARATION OF CONFORMITY

RF18-0060 Rev. B

We, MicroVention Europe SARL, located in France, 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: 514729 MRA (Annex II Section 4)
Full Quality Assurance: 487703 MR2 (Annex II Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN Code
Roadsaver Carotid Artery Stent System	See Page 2.	Class III– Annex 9, rule 8, subclause 2.	2018-12-30	45851 – Bare-metal carotid artery stent

Manufacturer	Notified Body	Production Site
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention, Inc.** 1311 Valencia Ave Tustin, CA 92780 USA **MicroVention Costa Rica, S.R.L.** Zona Franca Coyol Alajuela, Costa Rica

Intended Use: Roadsaver Carotid Arterial Stent is indicated for use in patients with carotid arterial atherosclerotic disease.

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.

DC18-01762

MicroVention Europe S.A.R.L. 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

Roadsaver Model Numbers:

Terumo Roadsaver	Stent Implant Unconstrained Dimensions	
Model Number	**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

Salvadore Palomares
Director, Regulatory Affairs
MicroVention

Saint-Germain-en-Laye, France
Place of Issue

18-JAN-2019
Date of Issue

Expiry Date: 2023-12-29

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 Artery Stent/Roadsaver Carotid Artery Stent

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:	ST18-003 CASPER Roadsaver STED.pdf dated 2018-09-20 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 2018-10-12 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	170761733
Effective date	2020-01-17
Expiry date	2023-12-29
Frankfurt am Main	2020-01-17

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 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 Devices 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	170736547
Effective date	2019-11-14
Expiry date	2022-11-13
Frankfurt am Main	2019-11-14

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

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	170758732
Effective date	2019-11-14
Expiry date	2024-05-26
Frankfurt am Main	2019-11-14

DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann
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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170758732
Effective date: 2019-11-14

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: 170758732
Effective date: 2019-11-14

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		
	LVIS™ EVO Intraluminal Support Device		
	FRED® Flow Re-Direction Endoluminal Devices	III	1,2,3
	FRED Jr.® Flow Re-Direction Endoluminal Devices		
	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
	PG Pro Peripheral Vascular Catheter	IIa	1,2
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

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170758732
Effective date: 2019-11-14

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France

Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	IIa	1,2