

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 <input checked="" type="checkbox"/> (Annex II.4) _____ 514729 MRA (Section 4) Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> (Annex II.3) _____ 487703 MR2 (Excluding Section 4) Certificate Number
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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	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 products from the signature date forward.

Signing Time: 9/21/2020 | 7:33:51 PM PDT
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Saint-Germain-en-Laye,
France

9/21/2020

Irina Kulinets
Sr. Vice President, Regulatory
Affairs, Quality, Clinical Research
MicroVention Europe SARL

Place of Issue

Date of Issue

Certificate Expiry Date: 2024-05-26

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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