

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.

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



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Place of Issue

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