EC DECLARATION OF CONFORMITY

FD14-0047, rev. B

We, MicroVention Europe, located in Saint-Germain-en-Laye, France 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
Standards	ISO 13485: 2003+AC:2009	Medical Devices – Quality management systems – Requirements for regulatory purposes
Conformity Assessment Route		Annex II, Section 4 - Full Quality System
Certificates #	**EC Design Examination:**	514729 MRA
	Full Quality Assurance:	487703 MR2

Product	Model Number(s)		Class-Rule	Effectivity date	GMDN Code
ROADSAVER™ Carotid Artery Stent System	RDS -0520-143RX RDS -0530-143RX RDS -0540-143RX RDS -0616-143RX RDS -0625-143RX RDS -0630-143RX RDS -0718-143RX RDS -0725-143RX RDS -0730-143RX	RDS -0820-143RX RDS -0825-143RX RDS -0830-143RX RDS -0840-143RX RDS -0920-143RX RDS -0930-143RX RDS -1020-143RX RDS -1030-143RX	III – Annex 9, rule 8	2014-04-07	45851

Manufacturer	**Notified Body**	**Production Site:**
MicroVention Europe 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 Avenue Tustin, CA 92780 – USA **MicroVention Costa Rica, S.R.L.** Zona Franca Coyol Alajuela, Costa Rica

Intended Use: The Carotid Artery Stent System is indicated for use in patients with atherosclerotic disease of the carotid 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.

Saint-Germain-en-Laye	01-July-2014
Place of Issue	Date of Issue

Sylvie Falaize
Manager Regulatory Affairs/Quality System
MicroVention Europe.

Expiry Date: 2018-12-26

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