EC DECLARATION OF CONFORMITY

RF18-0182, Rev. B

We, MicroVention, Inc., located in Tustin, California, USA, 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: 494215 MRA
Full Quality Assurance: 411133 MR2

Product	Model Number(s)	Class-Rule	GMDN Code
Scepter XC Occlusion Balloon	**BC0411XC**	III – Annex 9, rule 8	32584
Scepter C Occlusion Balloon	**BC0410C** **BC0415C** **BC0420C**		
Scepter Mini Occlusion Balloon	**BC0210M**		

Manufacturer	Notified Body	European Representative
MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention Europe** 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France

Intended Use: For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms. For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter Occlusion Balloon Catheter.

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.

I. Kulinets

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SVP Regulatory, Quality and Clinical
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