EC DECLARATION OF CONFORMITY

FD15-0038-C

We, MicroVention Europe, 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
Standards	EN ISO 13485: 2012 +AC:2012	Medical Devices – Quality management systems – Requirements for regulatory purposes
Conformity Assessment Route		Annex II (excl. section 4)

Product	Model Number(s)	Class-Rule	Effectivity (date)
HydroPearl	8HP2S75 8HP2S200 8HP2S400 8HP2S600 8HP2S800 8HP2S1100	IIb– Annex 9, rule 8	March 16, 2015

Manufacturer	**Notified Body**	**Production Site:**
MicroVention Europe 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	**Certificate # 487703 MR2** **DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention, Inc.** 1311 Valencia Avenue Tustin, CA 92780 USA

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.

Intended Use:

HydroPearl™ microspheres are intended to occlude blood vessels for therapeutic or adjunctive purposes in hypervascularized tumors, hepatocellular carcinoma, uterine fibroids, benign prostatic hyperplasia, peripheral arteriovenous malformations, tumors of the neck, torso and skeletal system, bleeding and trauma and pre-operative reduction of bleeding.

Sylvie Falaize
Manager Regulatory Affairs/Quality System
MicroVention Europe

Saint-Germain-en-Laye
Place of Issue

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