

EC DECLARATION OF CONFORMITY

FD15-0038/G

We, MicroVention Europe 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: ☐

EC Full Quality Assurance Certificate: ☒ 487703 MR2 (Excluding Section 4)

Product(s)	Model Numbers	Class-Rule	GMDN Code
HydroPearl™ Microspheres	See attached list	I Ib – Annex 9, Rule 8	60938

Manufacturer

MicroVention Europe, SARL.
30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France

Notified Body

DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297


Production Sites

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780 USA

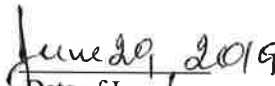
MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656 USA

Intended Use: The 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.

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 device(s) specified above distributed from the signature date forward.


Irina Kulinets
Sr. Vice President Regulatory Affairs,
Quality Assurance and Clinical Research
MicroVention, Inc.

Saint-Germain-en-Laye
Place of Issue


Date of Issue

Valid from signature date.

MicroVention Europe S.A.R.L. au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 -APE 46462 Siege Social : 30 bis, rue du Vieil Abreuvor - 78100 Saint-Germain-en-Laye
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Table 1: HydroPearl™ Microspheres

Product Codes	Microsphere Size (μm)	Volume of Microspheres (ml)	Volume of PBS (ml)
8HP2S75	75	2	4
8HP2S200	200	2	4
8HP2S400	400	2	4
8HP2S600	600	2	4
8HP2S800	800	2	4
8HP2S1100	1100	2	4