MicroVention TERUMO

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	IIb – Annex 9, Rule 8	60938

Manufacturer
MicroVention Europe, SARL.
30 bis, rue du Vieil Abreuvoir
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.

J. Kulinets

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

Saint-Germain-en-Laye
Place of Issue

June 20, 2019
Date of Issue

Valid from signature date.

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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

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 Abreuvoir - 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper- 78100 Saint-Germain-en-Laye
Tel. : +33 (0)1 39 21 77 46 - Fax : +33 (0)1 39 21 16 01 - E-mail: contact-europe@microvention.com

CERTIFICATE

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Devices and Microspheres.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	487703 MP2016
Certificate unique ID	170736547
Effective date	2019-11-14
Expiry date	2022-11-13
Frankfurt am Main	2019-11-14

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Catheters, Embolic Protection System, Aneurysm Embolization Devices and Microspheres as listed in Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	487703 MR2
Certificate unique ID	170758732
Effective date	2019-11-14
Expiry date	2024-05-26
Frankfurt am Main	2019-11-14

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170758732
Effective date: 2019-11-14

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America

2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela, Costa Rica

Annex to certificate
Certificate registration No.: 487703 MR2
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Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS Intraluminal Support Device	III	1,2,3
	LVIS Jr. Intraluminal Support Device		
	LVIS™ EVO Intraluminal Support Device		
	FRED® Flow Re-Direction Endoluminal Devices	III	1,2,3
	FRED Jr.® Flow Re-Direction Endoluminal Devices		
	CASPER™ RX Carotid Artery Stent System	III	1,2,3
	Roadsaver™ Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System	CASPER™ Peripheral Vascular Stent System	IIb	1,2,3
	RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever	ERIC ™ Retrieval Device	III	1,2,3
Liquid Embolic System	PHIL™ Liquid Embolic System	III	1,2
Catheter	SOFIA™ Distal Access Catheter	III	1,2,3
	SOFIA™ Select Catheter		1,2,3
	SOFIA™ PLUS Catheter		1,2,3
	SOFIA™ Flow PLUS Catheter		1,2,3
	SOFIA™ Guiding Catheter		1,2,3
	SOFIA™ Flow Catheter		1,2,3
	SOFIA® EX Catheter		1,2,3
	KANSHAS Drug Coated Balloon		1
	PG Pro Peripheral Vascular Catheter	IIa	1,2
Microspheres	HydroPearl Microspheres	IIb	1,2
	LifePearl Microspheres	III	1,2
	BioPearl® Microspheres	III	1,2
Embolic Protection Device (EPS)	Empro Embolic Protection System	III	1,2,3
	Nanoparasol Embolic Protection System		
Aneurysm Embolization Device	WEB™ Aneurysm Embolization System	III	1,2
Detachment Controller Units	WEB Detachment Controller	IIa	1,2

Annex to certificate
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France

Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	IIa	1,2

HydroPearl®

Compressible Microspheres for Embolization

HydroPearl® microspheres are PEG (polyethylene glycol), biocompatible, compressible, non-drug-loadable and calibrated embolisation microspheres. Available in a wide, color-coded range of sizes.

Due to its composition, HydroPearl® microspheres offer excellent properties and a tight calibration. HydroPearl® microspheres are intended to occlude blood vessels for therapeutic or adjunctive purposes in: hypervascularized tumors; hepatocellular carcinomas; uterine fibroids; benign prostatic hyperplasia; peripheral arteriovenous malformations; tumors of the neck, torso and skeletal system; bleeding, trauma and pre-operative reduction of bleeding.

Product Characteristics

- *Hydrogel technology based formulation[1]*
- *Tight calibration[2]*
- *Wide range of sizes*
- *More resilient microspheres[2]*

1 Polyethylene Glycol (PEG).
2 Data on file. Comparison with EmboSpheres, Merit Medical. Ref HPMCV-001.

General specifications

Volume of Microspheres	2 ml
Volume of PBS	4 ml

HydroPearl® microspheres are intented to occlude blood vessels for the Therapeutic and adjunctive Purposes. For complete list of indications, please refer to the instructions for use provided with the product. HydroPearl® microspheres are not commercially available in all countries. Please contact your Terumo local sales representative for more information. HydroPearl® microspheres is approved for U.S. sales. . MicroVention is a registered trademark of MicroVention, Inc. HydroPearl is a trademark of Terumo, Inc. Scientific and clinical data related to this document are on file at MicroVention, Inc.

Manufacturer MicroVention Europe - 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye FRANCE - Tel: +33(0)1 39 21 77 46 - Fax: +33(0)1 39 21 16 01. Distributed by: Terumo Europe N.V.

Item specifications

HydroPearl® microspheres Sizes	Colour	Code
75 ± 30 µm	Orange	8HP2S75
200 ± 75 µm	Yellow	8HP2S200
400 ± 75 µm	Blue	8HP2S400
600 ± 75 µm	Red	8HP2S600
800 ± 75 µm	Green	8HP2S800
1100 ± 75 µm	Purple	8HP2S1100

Please quote above item reference codes when placing an order

IS803/17GB1219KAVII