

EC DECLARATION OF CONFORMITY

RF18-0143, Rev. B

We, MicroVention, Inc., located in Tustin, California, USA 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

Conformity Assessment Route

EC Design Examination:

535858 MRA (Section 4)

Full Quality Assurance:

411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity Date	GMDN Code
WEB Aneurysm Embolization System	See attached list	III – Annex IX, Rule 8	2017-08-14	60940

Legal Manufacturer:

MicroVention, Inc.
1311 Valencia Avenue
Tustin, California 92780

Notified Body:

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

EU Representative:

MicroVention Europe, S.A.R.L.
30 bis, rue du Vieil Abreuvour
78100 Saint-Germain-en-Laye
France

Production Site:

Sequent Medical
11A Columbia
Aliso Viejo, California 92656

MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656

Intended Use: The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and un-ruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).

The WEB Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.

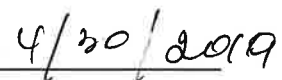
We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.



Irina Kulinets
Sr. VP RA/QA & Clinical Research
MicroVention, Inc.

Tustin, CA 92780, USA

Place of Issue



Date of Issue

Expiry Date: 2022-AUG-13

WEB Aneurysm Embolization System Model Numbers

Product	Model Number(s)				
WEB EV	W2-8-3	W2-9-4	W2-10-5	W2-11-6	
	W2-8-4	W2-9-5	W2-10-6	W2-11-7	
	W2-8-5	W2-9-6	W2-10-7	W2-11-8	
	W2-8-6	W2-9-7	W2-10-8	W2-11-9	
	W2-8-7	W2-9-8			
WEB EV	W2-8-S	W2-9-S	W2-10-S	W2-11-S	
WEB EV with 021 Delivery System	W4-4-3	W4-5-3	W4-6-3	W4-7-3	
	W4-4.5-3	W4-5.5-3	W4-6.5-3	W4-7-4	
	W4-4-4	W4-5-4	W4-6-4	W4-7-5	
	W4-4.5-4	W4-5.5-4	W4-6.5-4	W4-7-6	
		W4-5-5	W4-6-5	W4-7-7	
		W4-5.5-5	W4-6.5-5		
			W4-6-6		
			W4-6.5-6		
WEB EV with 021 Delivery System	W4-4-S	W4-5-S	W4-6-S	W4-7-S	
	W4-4.5-S	W4-5.5-S	W4-6.5-S		
WEB EV with 017 Delivery System	W5-3-2	W5-4.5-2	W5-5-5	W5-6-3.5	W5-6.5-5
	W5-3-2.5	W5-4.5-2.5	W5-5.5-2	W5-6-4	W5-6.5-5.5
	W5-3-3	W5-4.5-3	W5-5.5-2.5	W5-6-4.5	W5-6.5-6
	W5-3.5-2	W5-4.5-3.5	W5-5.5-3	W5-6-5	W5-7-2
	W5-3.5-2.5	W5-4.5-4	W5-5.5-3.5	W5-6.5-5	W5-7-2.5
	W5-3.5-3	W5-4.5-4.5	W5-5.5-4	W5-6-6	W5-7-3
	W5-3.5-3.5	W5-5-2	W5-5.5-4.5	W5-6.5-2	W5-7-3.5
	W5-4-2	W5-5-2.5	W5-5.5-5	W5-6.5-2.5	W5-7-4
	W5-4-2.5	W5-5-3	W5-5.5-5.5	W5-6.5-3	W5-7-4.5
	W5-4-3	W5-5-3.5	W5-6-2	W5-6.5-3.5	W5-7-5
	W5-4-3.5	W5-5-4	W5-6-2.5	W5-6.5-4	W5-7-5.5
	W5-4-4	W5-5-4.5	W5-6-3	W5-6.5-4.5	W5-7-6
WEB EV with 017 Delivery System	W5-4-S	W5-5-S	W5-6-S	W5-7-S	
	W5-4.5-S	W5-5.5-S	W5-6.5-S		