

EC DECLARATION OF CONFORMITY

RF18-0006 Rev. G
ECN Number: 22-03480

We, MicroVention Europe SARL, 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 <input checked="" type="checkbox"/> <u>(Annex II.4)</u> 535861 MRA Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> 487703 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
WEB Aneurysm Embolization System	Refer to Table 1 below	III – Annex 9, Rule 8	60940

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention Inc. 35 Enterprise Aliso Viejo, CA 92656 USA	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

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.

DocuSigned by:

 Signer Name: Julie Lopez-Genest
Signing Reason: I approve this document
Signing Time: 9/9/2022 | 9:12:23 AM PDT
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Julie Lopez-Genest
Sr Manager, RA & QA, EMEA
MicroVention Inc.

Saint-Germain-en-Laye, France
Place of Issue

9/9/2022

Date of Issue

Certificate Expiry Date: 2024-05-26

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Table 1: WEB Aneurysm Embolization System Model Numbers

Product	Model Number(s)				
WEB Aneurysm Embolization System with 027 Delivery System	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 Aneurysm Embolization System with 027 Delivery System	W2-8-S	W2-9-S	W2-10-S	W2-11-S	
WEB Aneurysm Embolization System 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 Aneurysm Embolization System 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 Aneurysm Embolization System 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	W5-6-6	W5-7-2.5
	W5-3.5-3	W5-4.5-4.5	W5-5.5-4	W5-6.5-2	W5-7-3
	W5-3.5-3.5	W5-5-2	W5-5.5-4.5	W5-6.5-2.5	W5-7-3.5
	W5-4-2	W5-5-2.5	W5-5.5-5	W5-6.5-3	W5-7-4
	W5-4-2.5	W5-5-3	W5-5.5-5.5	W5-6.5-3.5	W5-7-4.5
	W5-4-3	W5-5-3.5	W5-6-2	W5-6.5-4	W5-7-5
	W5-4-3.5	W5-5-4	W5-6-2.5	W5-6.5-4.5	W5-7-5.5
	W5-4-4	W5-5-4.5	W5-6-3	W5-7-6	
WEB Aneurysm Embolization System 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		