

EC DECLARATION OF CONFORMITY

RF19-0102 Rev. F

ECN Number: 22-03051

We, MicroVention, Inc., located in Tustin, California, USA, 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> 421268 MRA..... Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> 411133 MR2 (Excluding Section 4)..... Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
MicroPlex Platinum Coil System HydroCoil Embolic System	<i>See list on pages 2 and 3</i>	III – Annex IX, rule 8	60940

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 1311 Valencia Ave. Tustin, CA, 92780 United States of America	<u>MicroVention, Inc.</u> 1311 Valencia Ave Tustin, CA 92780, USA <u>MicroVention, Inc.</u> 35 Enterprise Aliso Viejo, CA 92656, USA <u>MicroVention Costa Rica SRL</u> Zona Franca Coyol Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvor 78100 Saint-Germain-en-Laye France

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:

Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 7/21/2022 | 12:09:28 PM PDT
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Amy Smith
VP, Global Regulatory Affairs
MicroVention, Inc.

Aliso Viejo, CA, USA
Place of Issue

12 July 2022
Date of Issue

Certificate Expiry Date: 2024-05-26

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Table 1: Catalog Numbers

MicroPlex 10 Platinum Coil System Endovascular Embolization Coil										MicroPlex 18 Platinum Coil System Endovascular Embolization Coil			
Cosmos 10	HyperSoft 3D	HyperSoft 3D (continued)	HyperSoft Helical	HyperSoft Helical (continued)	Helical 10 Soft	Helical 10 Soft (continued)	VFC	Compass 10	Complex 10	Cosmos 18	Compass 18	Helical 18 Soft	Complex 18
100202CSR-V	100102HS3D-V	100312HS3D-V	100101HS-V	100302HS-V	100202HCSR-S-V	100202HC-S-V	VFC010303-V	100203CM-V	100204CC-V	180617CS-V	180409CM-V	180204HC-S-V	180204CC-V
100254CSR-V	100103HS3D-V	100355HS3D-V	100102HS-V	100303HS-V	100203HCSR-S-V	100203HC-S-V	VFC061020-V	100203CMSR-V	100307CC-V	180619CS-V	180413CM-V	180208HC-S-V	180307CC-V
100306CSR-V	100106HS3D-V	100358HS3D-V	100103HS-V	100304HS-V	100204HCSR-S-V	100204HC-S-V	VFC061030-V	100254CM-V	100410CC-V	180723CS-V	180511CM-V	180304HC-S-V	180410CC-V
100408CSR-V	100115HS3D-V	100406HS3D-V	100104HS-V	100306HS-V	100206HCSR-S-V	100206HC-S-V	VFC101530-V	100254CMSR-V	100512CC-V	180827CS-V	180516CM-V	180308HC-S-V	180512CC-V
100412CSR-V	100152HS3D-V	100408HS3D-V	100105HS-V	100308HS-V	100208HCSR-S-V	100208HC-S-V	VFC101540-V	100304CM-V	100615CC-V	180931CS-V	180612CM-V	180406HC-S-V	180615CC-V
100515CSR-V	100153HS3D-V	100409HS3D-V	100106HS-V	100310HS-V	100303HCSR-S-V	100303HC-S-V	VFC152040-V	100304CMSR-V	100718CC-V	181036CS-V	180618CM-V	180410HC-S-V	180717CC-V
100518CSR-V	100154HS3D-V	100412HS3D-V	100151HS-V	100402HS-V	100304HCSR-S-V	100304HC-S-V	VFC152060-V	100355CM-V	100820CC-V	181139CS-V	180721CM-V	180512HC-S-V	180820CC-V
100522CSR-V	100155HS3D-V	100415HS3D-V	100152HS-V	100403HS-V	100306HCSR-S-V	100306HC-S-V	VFC030606-V	100355CMSR-V	100924CC-V	181243CS-V	180825CM-V	180615HC-S-V	180923CC-V
100618CSR-V	100202HS3D-V	100510HS3D-V	100153HS-V	100404HS-V	100308HCSR-S-V	100308HC-S-V	VFC030610-V	100408CM-V	101026CC-V	181347CS-V	180928CM-V	180520HC-R-V	181026CC-V
100622CSR-V	100203HS3D-V	100515HS3D-V	100154HS-V	100406HS-V	100310HCSR-S-V	100310HC-S-V	VFC030615-V	100408CMSR-V		181451CS-V	181030CM-V	180620HC-R-V	181128CC-V
100626CSR-V	100204HS3D-V	100520HS3D-V	100155HS-V	100408HS-V	100404HCSR-S-V	100404HC-S-V		100412CM-V		181652CS-V	181134CM-V	180730HC-R-V	181231CC-V
100722CSR-V	100206HS3D-V	100620HS3D-V	100156HS-V	100410HS-V	100406HCSR-S-V	100406HC-S-V		100412CMSR-V		181859CS-V	181237CM-V	180830HC-R-V	181332CC-V
100731CSR-V	100208HS3D-V	101510HS3D-V	100201HS-V	100506HS-V	100408HCSR-S-V	100408HC-S-V		100510CM-V		182065CS-V	181339CM-V	180930HC-R-V	181434CC-V
100825CSR-V	100210HS3D-V	102510HS3D-V	100202HS-V	100508HS-V	100410HCSR-S-V	100410HC-S-V		100510CMSR-V		182263CS-V	181443CM-V	181030HC-R-V	181639CC-V
100837CSR-V	100212HS3D-V	102512HS3D-V	100203HS-V	100510HS-V	100515HCSR-R-V	100515HC-R-V		100516CM-V		182468CS-V	181648CM-V	181230HC-R-V	181844CC-V
100933CSR-V	100254HS3D-V		100204HS-V	100606HS-V	100520HCSR-R-V	100520HC-R-V		100516CMSR-V			181855CM-V	181430HC-R-V	182050CC-V
101036CSR-V	100256HS3D-V		100206HS-V	100608HS-V	100615HCSR-R-V	100615HC-R-V		100612CM-V			182060CM-V	181630HC-R-V	
	100258HS3D-V		100208HS-V	100610HS-V	100620HCSR-R-V	100620HC-R-V		100612CMSR-V				181830HC-R-V	
	100304HS3D-V		100251HS-V	100808HS-V	100720HCSR-R-V	100720HC-R-V		100618CM-V				182030HC-R-V	
	100306HS3D-V		100252HS-V	100810HS-V	100730HCSR-R-V	100730HC-R-V		100618CMSR-V					
	100308HS3D-V		100253HS-V		100820HCSR-R-V	100820HC-R-V		100721CMSR-V					
	100310HS3D-V		100254HS-V		100830HCSR-R-V	100830HC-R-V		100824CMSR-V					
			100256HS-V		100920HCSR-R-V	100920HC-R-V		100928CMSR-V					
			100258HS-V		100930HCSR-R-V	100930HC-R-V		101030CMSR-V					
					101030HCSR-R-V	101030HC-R-V							
					100201HC-S-V								

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Table 2: Catalog Numbers (Continued)

HydroCoil 10 Embolic System Endovascular Embolization Coil				HydroCoil 18 Embolic System Endovascular Embolization Coil		
HydroFrame 10	HydroSoft Helical	HydroSoft Helical (continued)	HydroSoft 3D	HydroFill	HydroFill (continued)	HydroFrame 18
100405HFRM-V	100101H2HS-V	100506H2HS-V	100202HFRM-V	100202HFIL-V	101030HFIL-V	180619HFRM-V
100408HFRM-V	100102H2HS-V	100508H2HS-V	100254HFRM-V	100203HFIL-V	101120HFIL-V	180723HFRM-V
100410HFRM-V	100103H2HS-V	100510H2HS-V	100306HFRM-V	100204HFIL-V	101130HFIL-V	180827HFRM-V
100412HFRM-V	100104H2HS-V	100515H2HS-V	100102HFRM-V	100206HFIL-V	101140HFIL-V	180931HFRM-V
100415HFRM-V	100105H2HS-V	100520H2HS-V	100103HFRM-V	100304HFIL-V	101220HFIL-V	181036HFRM-V
100510HFRM-V	100151H2HS-V	100606H2HS-V	100152HFRM-V	100306HFIL-V	101230HFIL-V	181139HFRM-V
100515HFRM-V	100152H2HS-V	100608H2HS-V	100153HFRM-V	100404HFIL-V	101240HFIL-V	181243HFRM-V
100519HFRM-V	100153H2HS-V	100610H2HS-V	100154HFRM-V	100406HFIL-V	101330HFIL-V	181347HFRM-V
100520HFRM-V	100154H2HS-V	100615H2HS-V	100203HFRM-V	100408HFIL-V	101340HFIL-V	181445HFRM-V
100612HFRM-V	100155H2HS-V	100620H2HS-V	100204HFRM-V	100410HFIL-V	101350HFIL-V	181546HFRM-V
100619HFRM-V	100201H2HS-V	100715H2HS-V	100206HFRM-V	100508HFIL-V	101430HFIL-V	181644HFRM-V
100623HFRM-V	100202H2HS-V	100720H2HS-V	100208HFRM-V	100510HFIL-V	101440HFIL-V	181850HFRM-V
100626HFRM-V	100203H2HS-V	100730H2HS-V	100210HFRM-V	100515HFIL-V	101450HFIL-V	182048HFRM-V
100715HFRM-V	100204H2HS-V	100815H2HS-V	100256HFRM-V	100606HFIL-V	101630HFIL-V	182245HFRM-V
100723HFRM-V	100206H2HS-V	100820H2HS-V	100258HFRM-V	100608HFIL-V	101640HFIL-V	182450HFRM-V
100728HFRM-V	100208H2HS-V	100830H2HS-V	100304HFRM-V	100610HFIL-V	101650HFIL-V	
100731HFRM-V	100254H2HS-V	100920H2HS-V	100308HFRM-V	100615HFIL-V	101840HFIL-V	
100817HFRM-V	100256H2HS-V	100930H2HS-V	100310HFRM-V	100620HFIL-V	101850HFIL-V	
100826HFRM-V	100304H2HS-V	101020H2HS-V		100710HFIL-V	102040HFIL-V	
100833HFRM-V	100306H2HS-V	101030H2HS-V		100715HFIL-V	102050HFIL-V	
100836HFRM-V	100308H2HS-V			100720HFIL-V	102240HFIL-V	
100931HFRM-V	100310H2HS-V			100820HFIL-V	102250HFIL-V	
100933HFRM-V	100404H2HS-V			100830HFIL-V	102440HFIL-V	
101036HFRM-V	100406H2HS-V			100920HFIL-V	102450HFIL-V	
101139HFRM-V	100408H2HS-V			100930HFIL-V		