

EC DECLARATION OF CONFORMITY

RF19-0102 Rev. G
ECN Number: 22-03348

We, MicroVention, Inc., located in Aliso Viejo, 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 ☒ <u>(Annex II.4)</u> <u>421268 MRA</u> Certificate Number	EC Full Quality Assurance Certificate ☒ <u>(Annex II.3)</u> <u>411133 MR2 (Excluding Section 4)</u> Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
MicroPlex Platinum Coil System HydroCoil Embolic System	Refer to Table 1 below	Class III, Annex 9, Rule 8	60940

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 United States of America	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA MicroVention Costa Rica SRL Zona Franca Coyo Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 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: 8/24/2022 | 3:23:12 PM PDT
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Amy Smith VP, Global Regulatory Affairs MicroVention, Inc.	Aliso Viejo, CA, USA Place of Issue	8/24/2022 Date of Issue
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Certificate Expiry Date: 2024-05-26

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Table 1: Model 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
100202CSSR-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
100254CSSR-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
100306CSSR-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
100408CSSR-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
100412CSSR-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
100515CSSR-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
100518CSSR-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
100522CSSR-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
100618CSSR-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
100622CSSR-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
100626CSSR-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
100722CSSR-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
100731CSSR-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
100825CSSR-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
100837CSSR-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
100933CSSR-V	100254HS3D-V		100204HS-V	100606HS-V	100520HCSR-R-V	100520HC-R-V		100516CMSR-V			181855CM-V	181430HC-R-V	182050CC-V
101036CSSR-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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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		