

EC DECLARATION OF CONFORMITY

FD08-004 Rev AD

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: 421268 MRA (Section 4)

Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity Date	GMDN code
V-Trak®: MicroPlex® (MCS)	See attached list	III – Annex 9, rule 8	2017-01-20	60940
V-Trak®: HydroCoil® (HES)	See attached list			

**Manufacturer/
Production Site(s) :**

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780 USA

MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656 USA

MicroVention Costa Rica
Zona Franco Coyol
Alajuela, Costa Rica

EU Representative :

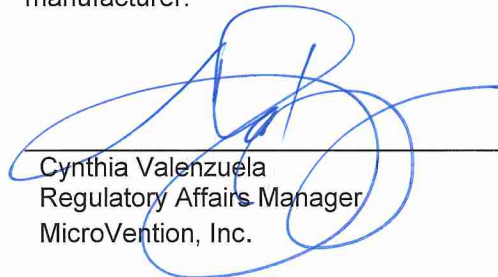
MicroVention Europe
30 bis, rue du Vieil Abrevoir
78100 Saint-Germain-en-Laye
France

Notified Body:

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

Intended Use: The MCS/HES device is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES 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 and for arterial and venous embolization in the peripheral vasculature.

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.



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Regulatory Affairs Manager
MicroVention, Inc.

Tustin, CA 92780, USA

Place of Issue

29 MAY 2018

Date of Issue

Expiry Date: 2022-JAN-19

MASTER

Model Numbers

MCS® and HES® V-Trak® Detachable Embolization Coil System

MicroPlex Coil System (MCS) Model Numbers									
MCS-Complex 1D 18	MCS-Compass (10)	MCS-Compass (18)	MCS Helical (18)	MCS-HyperSoft (10)	MCS-HyperSoft (10) (continued)	MCS-HyperSoft 3D	MCS-HyperSoft 3D (continued)	MCS-Helical (10) SR	MCS-Helical (10)
180204CC-V	100203CM-V	180409CM-V	180204HC-S-V	100101HS-V	100154HS-V	100115HS3D-V	100106HS3D	100202HCSR-S-V	100201HC-S-V
180307CC-V	100203CMSR-V	180413CM-V	180208HC-S-V	100102HS-V	100208HS-V	100102HS3D-V	101510HS3D	100203HCSR-S-V	100202HC-S-V
180410CC-V	100254CM-V	180511CM-V	180304HC-S-V	100103HS-V	100251HS-V	100103HS3D-V	100206HS3D	100204HCSR-S-V	100203HC-S-V
180512CC-V	100254CMSR-V	180516CM-V	180308HC-S-V	100104HS-V	100252HS-V	100152HS3D-V	100208HS3D	100206HCSR-S-V	100204HC-S-V
180615CC-V	100304CM-V	180612CM-V	180406HC-S-V	100105HS-V	100253HS-V	100153HS3D-V	100210HS3D	100208HCSR-S-V	100206HC-S-V
180717CC-V	100304CMSR-V	180618CM-V	180410HC-S-V	100106HS-V	100254HS-V	100154HS3D-V	100212HS3D	100303HCSR-S-V	100208HC-S-V
180820CC-V	100355CM-V	180721CM-V	180512HC-S-V	100155HS-V	100256HS-V	100155HS3D-V	100258HS3D	100304HCSR-S-V	100303HC-S-V
180923CC-V	100355CMSR-V	180825CM-V	180615HC-S-V	100156HS-V	100258HS-V	100202HS3D-V	102510HS3D	100306HCSR-S-V	100304HC-S-V
181026CC-V	100408CM-V	180928CM-V	180520HC-R-V	100201HS-V	100302HS-V	100203HS3D-V	102512HS3D	100308HCSR-S-V	100306HC-S-V
181128CC-V	100408CMSR-V	181030CM-V	180620HC-R-V	100202HS-V	100303HS-V	100204HS3D-V	100308HS3D	100310HCSR-S-V	100308HC-S-V
181231CC-V	100412CM-V	181134CM-V	180730HC-R-V	100203HS-V	100310HS-V	100254HS3D-V	100310HS3D	100404HCSR-S-V	100310HC-S-V
181332CC-V	100412CMSR-V	181237CM-V	180830HC-R-V	100204HS-V	100402HS-V	100256HS3D-V	100312HS3D	100406HCSR-S-V	100404HC-S-V
181434CC-V	100510CM-V	181339CM-V	180930HC-R-V	100206HS-V	100403HS-V	100304HS3D-V	100409HS3D	100408HCSR-S-V	100406HC-S-V
181639CC-V	100510CMSR-V	181443CM-V	181030HC-R-V	100304HS-V	100410HS-V	100306HS3D-V	100412HS3D	100410HCSR-S-V	100408HC-S-V
181844CC-V	100516CM-V	181648CM-V	181230HC-R-V	100306HS-V	100510HS-V	100355HS3D-V	100415HS3D	100515HCSR-R-V	100410HC-S-V
182050CC-V	100516CMSR-V	181855CM-V	181430HC-R-V	100308HS-V	100610HS-V	100358HS3D-V	100520HS3D	100520HCSR-R-V	100515HC-R-V
MCS Complex 2D 18	100612CM-V	182060CM-V	181630HC-R-V	100404HS-V	100808HS-V	100406HS3D-V	100620HS3D	100615HCSR-R-V	100520HC-R-V
180409CC-V	100612CMSR-V	MCS-Complex 2D 10	181830HC-R-V	100406HS-V	100810HS-V	100408HS3D-V	COSMOS 18	100620HCSR-R-V	100615HC-R-V
180512CC-V	100618CM-V	100306CC-V	182030HC-R-V	100408HS-V	Cosmos 10	100510HS3D-V	180619CS-V	100720HCSR-R-V	100620HC-R-V
180613CC-V	100618CMSR-V	100408CC-V	MCS-VFC	100506HS-V	100202CSSR-V	100515HS3D-V	180723CS-V	100730HCSR-R-V	100720HC-R-V
180716CC-V	100721CMSR-V	100511CC-V	VFC010303-V	100508HS-V	100254CSSR-V		180827CS-V	100820HCSR-R-V	100730HC-R-V
180819CC-V	100824CMSR-V	100613CC-V	VFC030606-V	100606HS-V	100306CSSR-V		180931CS-V	100830HCSR-R-V	100820HC-R-V
180921CC-V	100928CMSR-V	100716CC-V	VFC030610-V	100608HS-V	100408CSSR-V		181036CS-V	100920HCSR-R-V	100830HC-R-V
181024CC-V	101030CMSR-V	100819CC-V	VFC030615-V	100151HS-V	100412CSSR-V		181139CS-V	100930HCSR-R-V	100920HC-R-V
181227CC-V	MCS-CC-1D	100921CC-V	VFC061020-V	100152HS-V	100515CSSR-V		181243CS-V	101030HCSR-R-V	100930HC-R-V
181433CC-V	100204-CC-V	101024CC-V	VFC061030-V	100153HS-V	100518CSSR-V		181347CS-V		101030HC-R-V
181638CC-V	100307CC-V		VFC101530-V		100522CSSR-V		181451CS-V		
181843CC-V	100410-CC-V		VFC101540-V		100618CSSR-V		181652CS-V		
182049CC-V	100512CC-V		VFC152040-V		100622CSSR-V		181859CS-V		
	100615CC-V		VFC152060-V		100626CSSR-V		182065CS-V		
	100718CC-V				100722CSSR-V		182263CS-V		
	100820CC-V				100731CSSR-V		182468CS-V		
	100924CC-V				100825CSSR-V				
	101026CC-V				100837CSSR-V				
					100933CSSR-V				
					101036CSSR-V				

Model Numbers

MCS® and HES® V-Trak® Detachable Embolization Coil System

HydroCoil Embolic System (HES) Model Numbers									
HES - HydroFrame 10	HES - HydroFrame 18	HES-Helical (18)	HES-Helical (14)	HES-Helical (10)	HES - HydroSoft 3D	HES - HydroSoft	HES - HydroSoft Continued)	HydroFill (continued)	HydroFill (continued)
100405HFRM-V	180619HFRM-V	180610HES-V	140203HES-V	100202HES-V	100202HFRM-V	100101H2HS-V	100406H2HS-V	100510HFIL-V	100406HFIL-V
100408HFRM-V	180723HFRM-V	180710HES-V	140205HES-V	100204HES-V	100254HFRM-V	100102H2HS-V	100408H2HS-V	100515HFIL-V	100408HFIL-V
100410HFRM-V	180827HFRM-V	180810HES-V	140303HES-V	100206HES-V	100306HFRM-V	100103H2HS-V	100410H2HS-V	100608HFIL-V	100410HFIL-V
100412HFRM-V	180931HFRM-V	180815HES-V	140305HES-V	100302HES-V	100102HFRM-V	100104H2HS-V	100506H2HS-V	100610HFIL-V	100508HFIL-V
100415HFRM-V	181036HFRM-V	180820HES-V	140307HES-V	100304HES-V	100103HFRM-V	100105H2HS-V	100506H2HS-V	100615HFIL-V	101330HFIL-V
100510HFRM-V	181139HFRM-V	180910HES-V	140405HES-V	100306HES-V	100152HFRM-V	100151H2HS-V	100508H2HS-V	100620HFIL-V	101340HFIL-V
100515HFRM-V	181243HFRM-V	180915HES-V	140407HES-V	100308HES-V	100153HFRM-V	100152H2HS-V	100510H2HS-V	100710HFIL-V	101350HFIL-V
100519HFRM-V	181347HFRM-V	180920HES-V	140410HES-V	100404HES-V	100154HFRM-V	100153H2HS-V	100515H2HS-V	100715HFIL-V	101430HFIL-V
100520HFRM-V	181445HFRM-V	181010HES-V	140510HES-V	100406HES-V	100203HFRM-V	100154H2HS-V	100520H2HS-V	100720HFIL-V	101440HFIL-V
100612HFRM-V	181546HFRM-V	181015HES-V	140515HES-V	100408HES-V	100204HFRM-V	100155H2HS-V	100606H2HS-V	100820HFIL-V	101450HFIL-V
100619HFRM-V	181644HFRM-V	181020HES-V	140610HES-V	100410HES-V	100206HFRM-V	100201H2HS-V	100608H2HS-V	100830HFIL-V	101630HFIL-V
100623HFRM-V	181850HFRM-V	181215HES-V	140615HES-V	100504HES-V	100208HFRM-V	100202H2HS-V	100610H2HS-V	100920HFIL-V	101640HFIL-V
100626HFRM-V	182048HFRM-V	181220HES-V	140620HES-V	100506HES-V	100210HFRM-V	100203H2HS-V	100615H2HS-V	100930HFIL-V	101650HFIL-V
100715HFRM-V	182245HFRM-V	181415HES-V	140630HES-V	100508HES-V	100256HFRM-V	100204H2HS-V	100620H2HS-V	101020HFIL-V	101840HFIL-V
100723HFRM-V	182450HFRM-V	181420HES-V	140710HES-V	100510HES-V	100258HFRM-V	100206H2HS-V	100715H2HS-V	101030HFIL-V	101850HFIL-V
100728HFRM-V		181615HES-V	140715HES-V	100606HES-V	100304HFRM-V	100208H2HS-V	100720H2HS-V	101120HFIL-V	102040HFIL-V
100731HFRM-V		181620HES-V	140720HES-V	100608HES-V	100308HFRM-V	100254H2HS-V	100730H2HS-V	101130HFIL-V	102050HFIL-V
100817HFRM-V		181815HES-V	140730HES-V	100610HES-V	100310HFRM-V	100256H2HS-V	100815H2HS-V	101140HFIL-V	102240HFIL-V
100826HFRM-V		181820HES-V	140810HES-V	100203HES-V		100304H2HS-V	100820H2HS-V	101220HFIL-V	102250HFIL-V
100833HFRM-V		182015HES-V	140815HES-V			100306H2HS-V	100830H2HS-V	101230HFIL-V	102440HFIL-V
100836HFRM-V		182020HES-V	140820HES-V			100308H2HS-V	100920H2HS-V	101240HFIL-V	102450HFIL-V
100931HFRM-V		180304HES-V	140830HES-V			100310H2HS-V	100930H2HS-V	100202HFIL-V	100203HFIL-V
100933HFRM-V		180306HES-V	140910HES-V			100404H2HS-V	101020H2HS-V	100204HFIL-V	100404HFIL-V
101036HFRM-V		180406HES-V	140915HES-V				101030H2HS-V	100206HFIL-V	100606HFIL-V
101139HFRM-V		180408HES-V	140920HES-V					100304HFIL-V	
101243HFRM-V		180506HES-V	140930HES-V					100306HFIL-V	
		180508HES-V	141010HES-V						
		180606HES-V	141015HES-V						
		180608HES-V	141020HES-V						
		181230HES-V	141030HES-V						
		181430HES-V	140201HES-V						
		181630HES-V	140202HES-V						
		181830HES-V							
		182030HES-V							