

## 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 :**

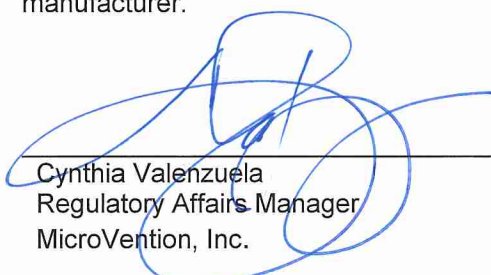
MicroVention Europe  
30 bis, rue du Vieil Abreuvor  
78100 Saint-Germain-en-Laye  
France

**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.



Cynthia Valenzuela  
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)<br>(continued) | MCS-HyperSoft 3D | MCS-HyperSoft 3D<br>(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      |                  |                  |                    |                 |                            |                       |                       |