



# EC Design Examination Certificate

## Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

### MicroVention, Inc.

1311 Valencia Ave.  
Tustin, CA, 92780  
United States of America

that the design of the following device(s)

### Embolization Protheses, Intravascular

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 411133 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** MCS HES Coils STED July 13 2020 dated 2020-07-13

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

**Examination report:**

411\_18e\_Report\_TFR\_MCS HES\_R2020\_V1 dated 2020-09-11

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no. 421268 MRA

Certificate unique ID 170771705

Effective date 2020-09-11

Expiry date 2024-05-26

Frankfurt am Main 2020-09-11

### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



**Annex to certificate**  
**Certificate registration No.: 421268 MRA**  
**Certificate unique ID: 170771705**  
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### **Categories of devices:**

MicroPlex Coil System (MCS) &  
HydroCoil Embolic System (HES) with  
V-Trak Delivery System

### **Devices:**

MicroPlex 10 Platinum Coil System (MCS)  
Endovascular Embolization Coil  
- Cosmos10  
- HyperSoft 3D  
- HyperSoft Helical  
- Helical 10  
- VFC  
- Compass 10  
- Complex 10

MicroPlex 18 Platinum Coil System (MCS)  
Endovascular Embolization Coil  
- Cosmos 18  
- Helical 18  
- Compass 18  
- Complex 18

HydroCoil 10 Embolic System (HES)  
Endovascular Embolization Coil  
- HydroFrame 10  
- HydroSoft Helical  
- HydroSoft 3D  
- HydroFill

HydroCoil 18 Embolic System (HES)  
Endovascular Embolization Coil  
- HydroFrame 18