



# 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)

### Headway Microcatheters in the variants as listed in Annex

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:** RF-17-0003C HW-W dated 2018-10-15  
RF17-0003D HW-W dated 2019-03-18  
RF17-0003E HW-W dated 2019-08-01

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

**Examination report:** 411\_18e\_Report\_TF\_Headway\_2018\_V1 dated 2019-12-08  
411\_18e\_Report\_TF\_Headway\_2018\_V2 dated 2019-03-22  
411\_18e\_Report\_TF\_Headway\_2018\_V3 dated 2019-11-10

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

Certificate registration no. 435827 MRA  
Certificate unique ID 170756608  
Effective date 2019-11-10  
Expiry date 2024-01-08  
Frankfurt am Main 2019-11-10

### 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.: 435827 MRA**  
**Certificate unique ID: 170756608**  
**Effective date: 2019-11-10**

**MicroVention, Inc.**

EGA Headway

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**Headway Microcatheters**

Headway 17 Advanced Microcatheter  
Headway 17 Advanced Soft Microcatheter  
Headway 21 Microcatheter  
Headway 27 Microcatheter  
Headway Duo Microcatheter  
Wedge Microcatheter