

# EC DECLARATION OF CONFORMITY

FD13-0059 / K

We, MicroVention Europe, located in Saint-Germain-en-Laye, France 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 Certificate:

502357 MRA (Section 4)

Full Quality Assurance Certificate:

487703 MR2 (Excluding Section 4)

| Product                                                 | Model Number(s) |            |            |            | Class-Rule            | Effectivity date | GMDN code |
|---------------------------------------------------------|-----------------|------------|------------|------------|-----------------------|------------------|-----------|
| FRED™ (Flow Re-Direction Endoluminal Device)            | FRED3507        | FRED4009   | FRED4513   | FRED5019   | III – Annex 9, rule 8 | 2018-03-10       | 46352     |
|                                                         | FRED3509        | FRED4012   | FRED4518   | FRED5026   |                       |                  |           |
|                                                         | FRED3511        | FRED4014   | FRED4524   | FRED5514   |                       |                  |           |
|                                                         | FRED3513        | FRED4017   | FRED5009   | FRED5519   |                       |                  |           |
|                                                         | FRED3516        | FRED4508   | FRED5011   | FRED5526   |                       |                  |           |
|                                                         | FRED4007        | FRED4511   | FRED5014   |            |                       |                  |           |
| Intraluminal Support Device                             | FRED3524        | FRED3536   | FRED4038   | FRED4539   |                       |                  |           |
|                                                         |                 | FRED4026   | FRED4528   | FRED5029   |                       |                  |           |
| FRED™ Jr. (Flow Re-Direction Endoluminal Device Junior) | FREDJR2508      | FREDJR2518 | FREDJR3010 | FREDJR3019 |                       |                  |           |
|                                                         | FREDJR2509      | FREDJR2519 | FREDJR3011 | FREDJR3020 |                       |                  |           |
|                                                         | FREDJR2510      | FREDJR2520 | FREDJR3012 | FREDJR3021 |                       |                  |           |
|                                                         | FREDJR2511      | FREDJR2521 | FREDJR3013 | FREDJR3022 |                       |                  |           |
|                                                         | FREDJR2512      | FREDJR2522 | FREDJR3014 | FREDJR3023 |                       |                  |           |
|                                                         | FREDJR2513      | FREDJR2523 | FREDJR3015 | FREDJR3024 |                       |                  |           |
| Intraluminal Support Device                             | FREDJR2514      | FREDJR2524 | FREDJR3016 | FREDJR3025 |                       |                  |           |
|                                                         | FREDJR2515      | FREDJR2525 | FREDJR3017 | FREDJR3026 |                       |                  |           |
|                                                         | FREDJR2516      | FREDJR2526 | FREDJR3018 | FREDJR3027 |                       |                  |           |
|                                                         | FREDJR2517      | FREDJR3009 |            |            |                       |                  |           |

| Manufacturer                                                                                 | Notified Body                                                                                   | Production Site                                                                                                                             |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| MicroVention Europe<br>30 bis, rue du Vieil Abreuvoir<br>78100 Saint-Germain-en-Laye, France | DQS Medizinprodukte GmbH<br>Notified Body Number: 0297<br>D-60433 Frankfurt am Main,<br>Germany | MicroVention, Inc.<br>1311 Valencia Av., Tustin, CA92780, USA<br>MicroVention Costa Rica, S.R.L.<br>Zona Franca Coyol, Alajuela, Costa Rica |

**Intended Use:** The FRED™ and FRED™ Jr. System is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED™ System may also be used with embolic coils for the treatment of intracranial neurovascular diseases.

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.



Salvatore Palomares  
Director, Regulatory Affairs  
MicroVention Europe

Saint-Germain-en-Laye

Place of Issue



Date of Issue

Expiry Date: 2021-11-30

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Prepared for Romania

MicroVention Europe S.A.R.L. au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z

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