



# EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

## MicroVention Europe SARL

30 bis, rue du Vieil Abreuvair  
78100 Saint-Germain-en-Laye  
France

that the design of the following device(s)

**FRED™ Flow Re-Direction Endoluminal Devices**  
**FRED Jr.™ Flow Re-Direction Endoluminal Devices**  
**FRED X™ Flow Re-Direction Endoluminal Devices**  
**FRED OMEGA™ Flow Re-Direction Endoluminal Devices**

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. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** FRED-FRED Jr STED.docx dated 2019-02-22  
FRED-FRED Jr-FRED X STED\_29Jan2020\_Clean Copy.docx dated 2020-01-29  
ST012 Rev B FRED Product family STED.pdf dated 2021-04-10

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

**Examination report:** 411\_18e\_Report\_TFR\_Sample\_Version 6.docx dated 2019-06-24  
411\_18e\_Report\_TFR\_FRED Change FRED X 2020.docx dated 2020-03-23  
411\_18e\_Report\_TFR\_FRED Change FRED OMEGA 2021.docx dated 2021-04-29

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

Certificate registration no. 502357 MRA  
Certificate unique ID 170775718  
Effective date 2021-04-29  
Expiry date 2024-05-26  
Frankfurt am Main 2021-04-29

## 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.