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 Abreuvoir
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.