# EC Design Examination Certificate

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

This is to certify that the manufacturer

## MicroVention Europe

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

that the design of the following device(s)

**SOFIA dDistal Access Catheter**
**SOFIA Select Catheter**
**SOFIA PLUS Catheter**
**SOFIA dFlow PLUS Catheter**
**SOFIA dGuiding Catheter**
**SOFIA dFlow Catheter**

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:** SOFIA Dossier Summary 06JAN2018 Final dated 2018-01-06

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

**Examination report:** 411_18e_Report_TFR_SOFIA_V1.docx dated 2018-04-21

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

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|---|---|
| Certificate registration no. | 487703 MRA |
| Certificate unique ID | 170713987 |
| Effective date | 2018-04-27 |
| Expiry date | 2023-04-26 |
| Frankfurt am Main | 2018-04-27 |

**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.**

Prepared for Romania