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)

SOFIA® Distal Access Catheter
SOFIA® Select Catheter
SOFIA® PLUS Catheter
SOFIA® Flow PLUS Catheter
SOFIA® Guiding Catheter
SOFIA® Flow Catheter
SOFIA® EX 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 STED Executive Summary dated 2019-06-28

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

Examination report: 411_18e_Report_TFR_SOFIA_R2019_V1 dated 2019-08-29

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

Certificate registration no.	487703 MRA
Certificate unique ID	170750277
Effective date	2019-08-29
Expiry date	2024-05-26
Frankfurt am Main	2019-08-29

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.