EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

that the design of the following device(s)

Scepter C™ Occlusion Balloon Catheter
Scepter XC™ Occlusion Balloon Catheter
Scepter Mini™ Occlusion Balloon 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. 411133 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: ST18-0008C - Technical Design Dossier For The Scepter Occlusion Balloon Catheters, April 2019 dated 2019-09-25

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

Examination report: 411_18e_Report_TFR_Scepter_R2020_V1 dated 2020-02-03

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

Certificate registration no.	494215 MRA
Certificate unique ID	170763222
Effective date	2020-02-03
Expiry date	2024-05-26
Frankfurt am Main	2020-02-03

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.