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)

Embolization Protheses, Intravascular

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: Tech_Dok_TCP_v0 dated 2015-03-31
Dossier MCS HES VTA 2.0 dated 2018-04-30

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

Examination report: 411_18e_Report_TFR_MCS HES_V1 dated 2017-01-02
411_18e_Report_TFR_MCS HES_V4.docx dated 2018-04-26

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

Certificate registration no.	421268 MRA
Certificate unique ID	170713953
Effective date	2018-04-27
Expiry date	2022-01-19
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.

Annex to certificate
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Categories of devices:	Devices:
V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical-Standard Helical-Reg. and Soft 10 & 18 - HyperSoft 10 & 3D - Complex-Complex 10 & 18, Compass 10 & 18 - COSMOS 10 & 18 - VFC HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18 - HydroFill - HydroSoft 3D - HydroSoft™ 10 - HydroFrame 10 & 18