

EC DECLARATION OF CONFORMITY

RF20-0015A (replacing FD08-011)

We, MicroVention, Inc., located in Tustin, California, USA, declare according to Directive 93/42/EEC Annex II under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Council Directive 93/42/EEC

Conformity Assessment Procedure Performed:

EC Design Examination Certificate <input checked="" type="checkbox"/> (Annex II.4) 435827 MRA Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> (Annex II.3) 411133 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
Headway 17 Advanced Soft Microcatheter	MC172150S	III – Annex 9, rule 7	10691
Headway 17 Advanced Microcatheter	MC172150STX, MC17215045X, MC17215090X, MC172150JX, MC172150SX		
Headway 21 Microcatheter	MC212150S, MC212156S		
Headway 27 Microcatheter	MC272150S, MC272156S		
Headway Duo Microcatheter	MC162156S, MC162167S		
Wedge Microcatheter	MCWED21160	III – Annex 9, rule 8	10691

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 1311 Valencia Ave. Tustin, CA, 92780 United States of America	MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780 USA MicroVention Costa Rica Zona Franca Coyol Alajuela, Costa Rica MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France

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We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.



Irina Kulinets
Sr. Vice President, Regulatory
Affairs, Quality, Clinical Research
MicroVention, Inc.

Tustin, CA, USA
Place of Issue

6/18/2020
Date of Issue

Certificate Expiry Date: 2024-01-08