EC DECLARATION OF CONFORMITY

RF 19-0097 Rev.B
DC Number: 20-05340

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, 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 ☒ (Annex II.4) 487703 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
SOFIA® Distal Access Catheter	DA5115ST, DA5125ST, DA6115ST	III – Annex 9, rule 7	58173 (Thrombectomy catheter)
SOFIA® PLUS Catheter	AC6115ST, AC6125ST, AC6131ST, DA6125ST, DA6131ST, DA6135ST		58173 (Thrombectomy catheter)
SOFIA® Flow PLUS Catheter	DA6125ST, DA6131ST		58173 (Thrombectomy catheter)
SOFIA® Flow Catheter	DA5115ST, DA5125ST, AC5115ST, AC5125ST		58173 (Thrombectomy catheter)
SOFIA® EX Catheter	ISC5105ST, ISC5115ST		17846 (Vascular guide catheter, Single Use)

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

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
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EC DECLARATION OF CONFORMITY

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.

DocuSigned by:
Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 11/19/2020 | 6:28:42 PM PST
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Irina Kulinets Sr. Vice President, Regulatory Affairs, Quality, Clinical Research MicroVention Europe SARL	Saint-Germain-en-Laye, France	11/19/2020
	Place of Issue	Date of Issue

Certificate Expiry Date: 2024-05-26

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