

# EC DECLARATION OF CONFORMITY

RF19-0097 Rev. D  
ECN Number: 23-02203

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:

<b>EC Design Examination Certificate</b> <input checked="" type="checkbox"/> <u>(Annex II.4)</u> <u>487703 MRA</u> <b>Certificate Number</b>	<b>EC Full Quality Assurance Certificate</b> <input checked="" type="checkbox"/> <u>(Annex II.3)</u> <u>487703 MR2</u> <b>Certificate Number</b>
---	---

Product	Model Number(s)	Class/Rule	GMDN Code
SOFIA® Distal Access Catheter	DA5115ST DA5125ST DA6115ST	Class III, Annex 9, Rule 7	17846
SOFIA® PLUS Catheter	DA6125ST DA6131ST DA6135ST		
SOFIA® EX Catheter	ISC5105ST ISC5115ST		
SOFIA® Flow Catheter	DA5115ST DA5125ST		58173
SOFIA® Flow PLUS Catheter	DA6125ST DA6131ST		

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 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

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.

## EC DECLARATION OF CONFORMITY

---

DocuSigned by:  
Amy Smith  
5/16/2023

---

 Signer Name: Amy Smith  
Signing Reason: I approve this document  
Signing Time: 5/16/2023 | 12:51:34 PM PDT  
VP, Global Regulatory Affairs  
6A007ED64EB548A7E8E3F9AB77A2F27F6  
MicroVention Europe SARL

---

Saint-Germain-en-Laye, France  
Place of Issue

---

Date of Issue

**Certificate Expiry Date: 2024-05-26**