EC DECLARATION OF CONFORMITY

RF 19-0053 Rev. C

DC Number: 20-06556

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) 524858 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
Empro™ Embolic Protection System	EP4514C-190 EP6514C-190	III – Annex 9, rule 7	58112

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.

DocuSigned by:
Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 10/15/2020 | 5:36:47 PM PDT
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Saint-Germain-en-Laye, France	10/15/2020
Place of Issue	Date of Issue

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

Certificate Expiry Date: 2024-05-26