EC DECLARATION OF CONFORMITY

RF18-0147, Rev. B

We, MicroVention, Inc., located in Tustin, California, USA declare according to Directive 93/42/EEC Annex II (incl. section 4.) 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.

Directives:	93/42/EEC Council Directive Concerning Medical Devices
Conformity Assessment Route:	
EC Design Examination:	535858 MRA (Section 4)
Full Quality Assurance:	411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity Date	GMDN Code
WEB Detachment Controller	WDC-1, WDC-2	IIa – Annex IX, Rule 9	2019-04-04	43978

Legal Manufacturer:
MicroVention, Inc.
1311 Valencia Avenue
Tustin, California 92780

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

European Representative:
MicroVention Europe, S.A.R.L.
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Sequent Medical, Inc.
11A Columbia
Aliso Viejo, California 92656

MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656

Intended Use: The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).
The WEB Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

J. Kulinets

Irina Kulinets
Sr. VP RA/QA & Clinical Research
MicroVention, Inc

Tustin, CA 92780, USA

Place of Issue

4/30/2019

Date of Issue

Expiry Date: 2022-11-02

MicroVention Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com