EC DECLARATION OF CONFORMITY

FD14-0031, Rev. G

We, MicroVention Europe SAR, located in Saint-Germain-en-Laye, France 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	Annex II, Section 4 – Full Quality System
EC Design Examination: **Full Quality Assurance:**	517356 MRA Annex II (Section 4) 487703 MR2 Annex II (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
PHIL™ Liquid Embolic System	LEN10250 LEN10250RE LEN10300 LEN10300RE LEN10350 LEN10350RE LEN10LV250 LEN10LV250RE	III – Annex 9, rule 8	2019-03-08	60939

Manufacturer	Notified Body	Production Site
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention, Inc.** 1311 Valencia Avenue Tustin, CA 92780, USA **Microvention, Inc.** 35 Enterprise Aliso Viejo, CA 92656, USA

Intended Use: The PHIL™ Liquid Embolic System is intended for use in the embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

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 Regulatory, Clinical, Quality
MicroVention Europe SARL

Saint-Germain-en-Laye
Place of Issue

4/12/2019
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MASTER

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